

# Community Engagement & Ethical Practice in Vaccine Research



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Thesis submitted for the degree of PhD

***Declaration of Authorship***

*'I, Tracey Chantler, confirm that the work presented in this thesis is my own. Where information has been derived from other sources, I confirm that this has been indicated in the thesis.'*



**Tracey Chantler**

# Abstract

Community Engagement (CE) is often presented by bio-ethicists and scientists as a straightforward and unequivocal good which can help to minimize the risks of exploitation, ensure a fair distribution of research benefits and improve the quality of informed consent in the conduct of health research in developing countries. The main objective of my thesis is to critically analyse the relationship between CE and ethical practice in vaccine research. I do this by drawing on ethnographic fieldwork undertaken between 2007 and 2009. In my fieldwork I explored how CE is understood, talked about and enacted in two paediatric vaccine trials conducted by a collaborative partnership between the Kenyan Medical Research Institute and the US Centers for Disease Control (KEMRI/CDC) in Western Kenya.

The first 3 chapters of my thesis contain introductory material. Chapter 1 describes the geographic and institutional context of my fieldwork and provides a summary of the paediatric vaccine trials. It also documents my conceptual framework with reference to relevant literature. Chapter 2 provides an overview of the history of immunization and related research in Sub-Saharan African, with a particular focus on East Africa. In chapter 3 I describe my ethnographic research design and provide a detailed account of my fieldwork, methods and data analysis. 122 people from the following groups consented to participate in this study: 1) KEMRI/CDC Staff Members (n=18), 2) Community Representatives (e.g. Village Reporters (VRs), Community Advisory Board (CAB), Government & Political Gatekeepers) (n=71), 3) Parents/Guardians of Vaccine Trial Participants (n=20), and 4) Other Community Members (n=7). With the support of 3 Kenyan research assistants I observed CE related activities, compiled field notes and conducted 83 semi-structured interviews and 7 focus group discussions.

The 8 findings chapters are grouped as follows: 1) 'The Historical Emergence & Framing of Community Engagement' (Ch. 4-5); 2) 'The Social Construction of Community Engagement' (Ch. 6-9); and 3) 'Responses and Negotiations in Community Engagement' (Ch. 10-11).

- 1) Between the years of 1979-2009 the KEMRI/CDC research programme grew from involvement in community-led health projects into a global enterprise. This inevitably resulted in changes in the control and direction of interactions between researchers and community members. The contemporary framing of CE relies heavily on researchers teaching laypeople about science.
- 2) The concept of 'positioning' is critical to the contemporary social construction of CE. KEMRI/CDC's primary goal is to convey accurate messages, present a positive image and demonstrate 'attachment' to the local community. VRs' (paid volunteers) smooth the passage of research but find it difficult to balance allegiances, and respond to local expectations for material assistance. CAB members function as KEMRI/CDC patron-clients rather than community advocates, and Gatekeepers argue that a research agenda cannot be applied without accounting for inadequate district health services.
- 3) Increasing interactions between KEMRI/CDC and the community have helped address inherent cultural suspicions about research, thereby diverting attention to the benefits of trial participation. Hence questions of exclusion rather than inclusion have started to dominate discussions during CE activities. When it comes to engagements in public health facilities attention is focussed on how to balance differences between two paradigms of care-giving; namely 1) 'research' and 'general' care.

In chapter 12 I synthesize my findings and argue that far from being an unproblematic good CE offers a lens into new and pre-existing inequalities which affect the implementation of research in resource-limited settings. CE emerges from my data as highly complex and challenging work, which requires continuous efforts and cannot be limited simply to information exchange. In order to address the tensions and contradictions which arise in CE it is essential to discuss questions of social justice and to engage materially, through a broader distribution of resources, with the community where research takes place.

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## Research Assistants

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## Study Participants

KEMRI/CDC current staff members, Village reporters, Community advisory board members, Health facility representatives, Government administrators and elected representatives, Parents of vaccine trial participants, Community members, People affiliated with KEMRI/CDC in the past.

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*The Lord is faithful to all his promises and loving towards all he has made.*

*Those who hope in the Lord will renew their strength.*

*They will soar on wings like eagles;*

*they will run and not grow weary,*

*they will work and not be faint.*

***Psalm 145 v 13b & Isaiah 41 v 31***

# Table of Contents

## The Thesis

### Introduction

Title Page .....	p. 1
Declaration of Authorship .....	p. 2
Abstract .....	p. 3
Acknowledgements .....	p. 5
Table of Contents .....	p. 7
Glossary of Abbreviations.....	p. 10
Chapter 1: Thesis Overview: Object of Study and Conceptual Framework .....	p. 11
Chapter 2: History of Immunization & Vaccine Research in Sub-Saharan Africa..	p. 39
Chapter 3: Research Design, Methods and Fieldwork .....	p. 57

### Findings

#### The Historical Emergence and Framing of Community Engagement

Chapter 4: The History of Community Relations at KEMRI/CDC .....	p. 77
Chapter 5: The Framing of Community Engagement at KEMRI/CDC .....	p. 98

#### The Social Construction of Community Engagement

Chapter 6: KEMRI/CDC Staff Perspectives on Community Engagement .....	p. 119
Chapter 7: Village Reporters' Perspectives on Community Engagement .....	p. 141
Chapter 8: Community Advisory Board Members' Perspectives on Community Engagement .....	p. 165
Chapter 9: Gatekeepers' Perspectives on Community Engagement .....	p. 194

#### Responses and Negotiations in Community Engagement

Chapter 10: Diverse & Changing Community Responses to Vaccine Trials .....	p. 226
Chapter 11: Community Engagement in Public Health Facilities .....	p. 259

### Synthesis of Findings

Chapter 12: Summary & Conclusion .....	p. 280
References: .....	p. 289

## Illustrations

### Figures

1. The COW POCK or the Wonderful Effects of the New Inoculation ..... p. 44
2. Personnel & Community Intermediaries involved in CE at KEMRI/CDC ..... p.106

### Maps

1. Nyanza Province, Kenya, East Africa ..... p. 13
2. The KEMRI/CDC Health and Demographic Surveillance Area ..... p. 14

### Photos

1. Community Engagement Meeting outside a Health Clinic in Karemo..... p. 1
2. Aerial View of the KEMRI-CGHR and KEMRI/CDC Grounds at Kisian ..... p. 16
3. Landscape View of the KEMRI-CGHR & KEMRI-CDC Facilities ..... p. 17
4. The KEMRI/CDC Science Wing ..... p. 18
5. HDSS Household Location Code Marked on the Door of a House..... p. 87
6. Notice Boards at Chief's Camps in Siaya District (a) ..... p. 94
7. Notice Boards at Chief's Camps in Siaya District (b) ..... p. 94
8. Informal Discussion after a VR Meeting ..... p. 110
9. The Kisumu CAB (mainly serves the HIV Research Branch) ..... p. 111
10. Chief's Baraza in Siaya Town, May 2009 (a) ..... p. 112
11. Chief's Baraza in Siaya Town, May 2009 (b) ..... p. 112
12. CLVT talking about the MVT before it started with a women's group ..... p. 113
13. Meeting with mothers to boost recruitment after start of MVT ..... p. 113
14. Administrative Chiefs in Uniform ..... p. 197
15. Social Situation 4<sup>th</sup> Annual Chief's Day: 'Together we can' ..... p. 201
16. Social Situation 4<sup>th</sup> Annual Chief's Day: Partnership Award ..... p. 204
17. Groundbreaking for new Clinical Research Centre at SDH, May 2009 ..... p. 209
18. Kogelo Health Dispensary ..... p. 212
19. A man from Kogelo touching a portrait of Obama ..... p. 213
20. Posters about the MVT on a shop next to the entrance of SDH (a) ..... p. 250
21. Posters about the MVT on a shop next to the entrance of SDH (b) ..... p. 250
22. Maternal Child Health Clinic, SDH (a) ..... p. 250
23. Maternal Child Health Clinic, SDH (b) ..... p. 250
24. SDH Paediatric Ward ..... p. 269

### Tables

1. Number of Study Participants, SSIs and FGDs ..... p. 64
2. Working conditions & qualifications required for paid jobs at KEMRI/CDC ..... p. 107



3. KEMRI/CDC Staff Members, Study Participant Details .....	p. 311
4. Community Advisory Board Member, Study Participant Details .....	p. 312
5. Village Reporter, Study Participant Details .....	p. 313
6. Gatekeepers, Study Participant Details .....	p. 314
7. Health Facility Partners, Study Participant Details .....	p. 315
8. Parent/Guardians RVT Participants, Study Participant Details .....	p. 317
9. Parent/Guardians RVT Participants, Study Participant Details .....	p. 317
10. Community Members, Study Participant Details .....	p. 318

## **Text Boxes**

1. Milestones in Immunization .....	p. 41
2. Definition of a Village Reporter .....	p. 146
3. CAB Members' Definitions of Community Engagement, November 2008 .....	p. 178
4. Types of Questions CAB members are asked .....	p. 190
5. Types of Questions Asked at Public Forums, Jan-Sept2009 .....	p. 247

## **Appendices**

### **I. Research Background & Methods**

1. Centers for Disease Control: Principles of Community Engagement .....	p. 310
2. Study Participant Details .....	p. 311
3. Field Notes Excerpt, February 2007 .....	p. 319
4. AIDS vaccine conference in South Africa in October 2008, Poster .....	p. 322
5. Chronology of Community Engagement in the Vaccine Trials .....	p. 324
6. Comparative Observation Tools .....	p. 328
7. RSTMH Biennial Meeting September 2012, Abstract: .....	p. 338
<i>'We can't involve everyone': A Comparative Case study of Community Engagement Processes at two Malaria Vaccine Trial Sites in Kenya</i>	

### **II. Research Findings**

1. Big Issue Article .....	p. 341
2. KEMRI/CDC Standard Operating Procedure: Community Engagement .....	p. 343
3. KEMRI/CDC Standard Operating Procedure No. 11: Village Reporters .....	p. 349
4. Newsletter for the KEMRI/CDC Community: Dound Oganda .....	p. 351
5. Appointment Letter for a CAB member .....	p. 356
6. CAB Training Materials .....	p. 359
7. Chiefs' Charter of Service .....	p. 373
8. Malaria Vaccine Trial Power-point Presentation .....	p. 375
9. Memorandum of Understanding between SDH and KEMRI/CDC .....	p. 379

# Glossary of Abbreviations

<b>CAB:</b>	<b>Community Advisory Board</b>
<b>CDC:</b>	<b>United States Centers for Disease Control &amp; Prevention</b>
<b>CE:</b>	<b>Community Engagement</b>
<b>CGHR:</b>	<b>Centre for Global Health Research</b>
<b>CLO:</b>	<b>Community Liaison Officer</b>
<b>CLVT:</b>	<b>Community Liaison for Vaccine Trials</b>
<b>CM:</b>	<b>Community Member</b>
<b>CO:</b>	<b>Communications Officer</b>
<b>CR:</b>	<b>Community Representative</b>
<b>CRC:</b>	<b>Clinical Research Centre</b>
<b>CT:</b>	<b>Communications Team</b>
<b>DC:</b>	<b>District Commissioner</b>
<b>DO:</b>	<b>District Officer</b>
<b>EPI:</b>	<b>Expanded Programme of Immunization</b>
<b>FGDs:</b>	<b>Focus Group Discussions</b>
<b>FWs:</b>	<b>Fieldworkers</b>
<b>GOK:</b>	<b>Government of Kenya</b>
<b>HDSS:</b>	<b>Health and Demographic Surveillance System</b>
<b>HDSA:</b>	<b>Health and Demographic Surveillance Area</b>
<b>KEMRI:</b>	<b>Kenyan Medical Research Institute</b>
<b>KEMRI/CDC:</b>	<b>KEMRI &amp; United States Centres for Disease Control &amp; Prevention</b>
<b>KEPI:</b>	<b>Kenyan Expanded Programme of Immunization</b>
<b>Ksh:</b>	<b>Kenyan Shillings</b>
<b>MOH:</b>	<b>Ministry of Health</b>
<b>MOU:</b>	<b>Memorandum of Understanding</b>
<b>MP:</b>	<b>Malaria Vaccine Trial Participant</b>
<b>MVT:</b>	<b>Malaria Vaccine Trial</b>
<b>PAVE:</b>	<b>Partnership for Aids Vaccine Evaluation</b>
<b>PHC:</b>	<b>Primary Health Care</b>
<b>PI:</b>	<b>Principal Investigator</b>
<b>RP:</b>	<b>Rotavirus Vaccine Trial Participant</b>
<b>RS:</b>	<b>Research Staff</b>
<b>RVT:</b>	<b>Rotavirus Vaccine Trial</b>
<b>SDH:</b>	<b>Siaya District Hospital</b>
<b>SOP:</b>	<b>Standard Operating Procedure</b>
<b>SSA:</b>	<b>Sub-Saharan Africa</b>
<b>SSIs:</b>	<b>Semi-Structured Interviews</b>
<b>US:</b>	<b>United States</b>
<b>VRs:</b>	<b>Village Reporters</b>
<b>WHO:</b>	<b>World Health Organisation</b>

## Chapter 1:

### Thesis Overview: Object of Study & Conceptual Framework

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*'A collaborative partnership between researchers and sponsors in developed countries and researchers, policy makers, and communities in developing countries helps to minimize the possibility of exploitation by ensuring that a developing country determines for itself whether the research is acceptable and responsive to the community's health problems (Participants in the Conference on Ethical Aspects of Research in Developing Countries, 2002). Moreover, without the engagement of researchers and host communities in the developing country, a study is unlikely to have any lasting impact, and, without the investment of makers of health policies, the research results are unlikely to influence policy making and the allocation of scarce health-care resources'.*

**Excerpt from Emanuel et al. (2004) Paper: *What Makes Clinical Research in Developing Countries Ethical? The Benchmarks of Ethical Research***

## Introduction

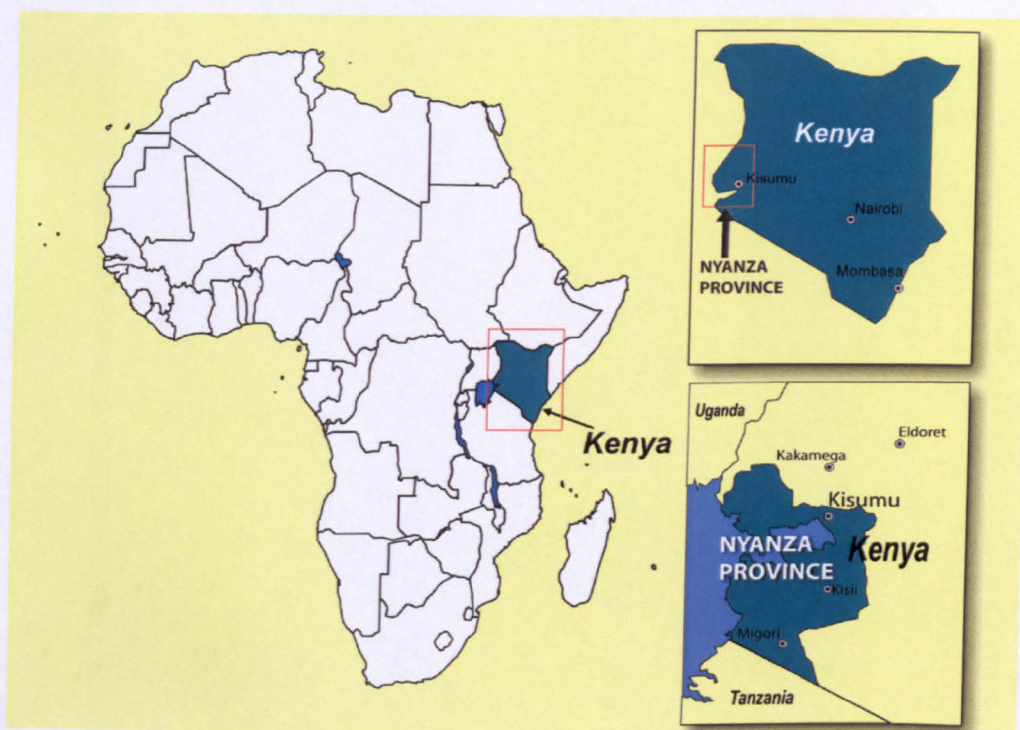
The purposes of this chapter are to define and describe the object of study of this thesis, namely the relationship between community engagement and ethical practice in the conduct of bio-medical research in resource-limited settings, and to provide an overview of the thesis structure and a summary of the core findings. The first section sets out the premise of this research, describes the geographic and institutional context of my fieldwork and introduces the two vaccine trial case studies. This is followed by an account of my interest in the object of study and a review of the key literature which informed the focus of my ethnographic enquiry. Finally I provide an outline of the thesis and a synopsis of the main questions addressed in my findings chapters and the core findings which cut across these chapters.

## **The Object of Study**

My object of study is the understandings and practices of community engagement (CE) in international health research conducted in resource-limited settings. I studied this in the context of two paediatric vaccine trials run by the Kenyan Medical Research Institute in collaboration with the US Centers for Disease Control and Prevention (KEMRI/CDC) in Western Kenya. The conduct of such research in vulnerable target groups raises important ethical considerations regarding participants' understanding of research, voluntariness, coercion, the potential exploitation of trial participants, benefit sharing and the social value of research. CE and associated collaborative partnerships between researchers and communities have been proposed as a benchmark for ethical research and a tool for addressing such concerns (Emanuel et al., 2004). In the Emanuel et al. (2004) framework CE is presented as an unproblematic and unequivocal good which can help to minimize the risks of exploitation, ensure a fair distribution of research benefits and improve the quality of informed consent in the conduct of health research in developing countries. By means of ethnographic fieldwork undertaken between 2007 and 2009 I explored how CE is understood, talked about and enacted in the implementation of two paediatric vaccine trials undertaken by KEMRI/CDC. The thesis argues that, in this setting, CE needs to be understood within the context of historical models for working with target communities, and the long-standing and developing relationships between researchers, their staff and assistants and members of the wider community in which trials take place. Furthermore, far from being an unproblematic good in terms of ethical practice, CE offers a lens into new and pre-existing inequalities which affect the implementation of research in this kind of setting. CE emerges from my data as complex and challenging work, which requires continuous efforts and cannot be limited simply to information exchange. In order to address the tensions and contradictions which arise in CE it is essential to discuss questions of social justice and to engage materially, through a broader distribution of resources, with the community where research takes place.

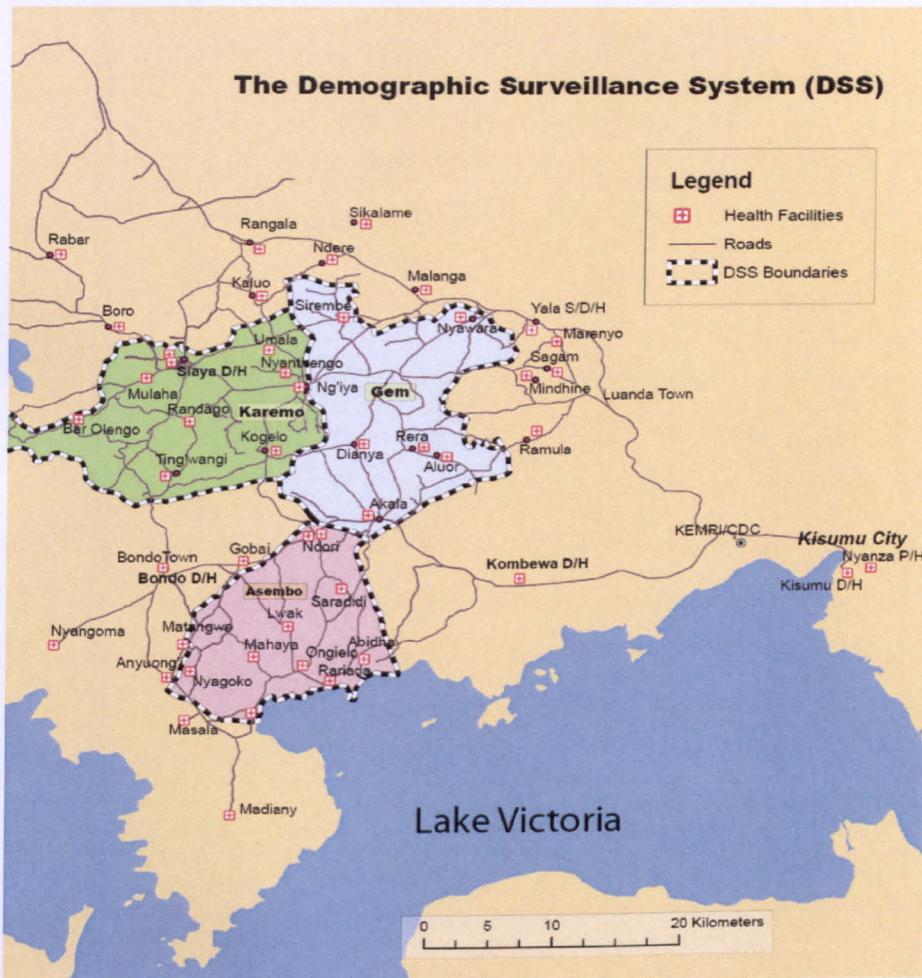
## The Study Site

I conducted my ethnographic fieldwork in Karemo Division where the paediatric vaccine trials conducted by KEMRI/CDC were taking place. Karemo Division is part of Siaya District and is located an hour's drive north-west from Kisumu, the provincial capital of Nyanza. Nyanza Province is located in Western Kenya and borders Uganda and Tanzania.



**Map 1: Nyanza Province, Kenya, East Africa**

The main offices of KEMRI/ CDC are situated on the outskirts of Kisumu. Karemo Division (shaded in green in Map 2) is a rural area within Siaya District which forms part of the KEMRI/CDC Health and Demographic Surveillance System (HDSS). This system includes the three areas highlighted in the above map, and serves as a platform on which to base a range of studies to examine specific disease issues, including descriptive epidemiology, diagnosis, treatment, prevention, behaviour, and economics. Surveillance of households is carried out by trained FWs every four months, and in 2008 a total of 54,367 households provided demographic, health and socio-economic data (KEMRI/CDC Health and Demographic Surveillance System (HDSS), 2008).



**Map 2: The KEMRI/CDC Health and Demographic Surveillance Area**

Health indicators are poor in the health and demographic surveillance area. Immunisation coverage in 2008 was well below the World Health Organisation (WHO) target of 90% with only 74% of children under 2 years of age being fully immunised, the highest coverage was in Karemo, at 81%. The infant and under-five mortality ratios are 110.5/1,000 live births and 202.8/1,000 live births respectively and average life expectancy at birth is 45 years (42 years for men and 47 for women) - which is lower than the national figure of 53 years (KEMRI/CDC Health and Demographic Surveillance System (HDSS), 2008). HIV is twice as prevalent as the national average of 7.1% (National AIDS/STI Control Programme (NASCO), September 2009) and, in spite of the successful implementation of an HIV care and treatment

programme, AIDS-related mortality and suffering affects almost every family in the area (Prince and Geissler, 2010). In 2008 the major causes of death in adults living in the areas where the HDSS operated were HIV and Tuberculosis. In contrast, among children, aged 0-11 years, malaria was the leading cause of mortality accounting for 27% of deaths, followed by HIV (14%) and malnutrition (12%) (KEMRI/CDC Health and Demographic Surveillance System (HDSS), 2008).

Inhabitants of the HDSA mainly engage in farming, fishing and petty trade, and it is estimated that 64-74% of the population live below the poverty level (Kenya Central Bureau of Statistics, 2005). In 2008, 63% of the household heads reported to be engaged in subsistence farming, 13% reported to be engaged in small businesses (kiosk, jua-kali<sup>1</sup> and selling maize) and only 5% were salaried employees. Among the resident population aged 18 years and above, 64% had at least primary education, 23% had secondary education and only 13% had no education at all. Over three-quarters of houses surveyed in the HDSA in 2008 were mud houses, while 12% were semi-permanent (houses built with mud and plastered with cement), and 11% were permanent houses (house built of cement blocks or burnt bricks). Half of the households surveyed owned livestock and the number of cattle ranged from 1 to 110 with a median of 3 cattle per household. Access to safe water is a major challenge in the HDSA with approximately 90% of the households having no access to safe water sources and 44% of households using untreated water.

### **The KEMRI/CDC Public Health and Research Collaboration**

The Kenyan Medical Research Institute (KEMRI) and the United States Centres for Disease Control and Prevention (CDC) have been working together since 1979. In Western Kenya this collaboration is officially termed the KEMRI/CDC Public Health Research Collaboration, is generally referred to as 'KEMRI/CDC' or simply 'CDC'. The KEMRI/CDC offices are situated within secure grounds which belong to the KEMRI Centre for Global Health Research (CGHR). These grounds are located in a rural area called Kisian, which is 20 minutes' drive from Kisumu. The grounds house the KEMRI-CGHR offices, offices used by other research

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<sup>1</sup> Small-scale craft or artisanal work, such as making tools or textiles-literal translation: 'in the hot sun'

groups collaborating with KEMRI-CGHR, the extensive KEMRI/CDC science wing, transport offices and garages, and modern laboratory facilities. The grounds are very well landscaped and maintained and cordoned off by a high concrete wall. In order to enter the grounds one must pass through 2 security gates. These gates are manned by contracted security guards from a multinational security firm. On arrival at the gates one either has to show proof of employment status or have been registered as a visitor in order to be granted access. KEMRI/CDC employees are required to wear identification at work and have to swipe their ID cards to enter the KEMRI/CDC science wing and laboratories. The layout shown in the aerial view of the KEMRI-CGHR and KEMRI/CDC grounds below illustrates how the research centre is cordoned off from the surrounding areas. The following photographs provide evidence the size of the complex and the quality of the buildings, particularly those used by KEMRI/CDC.



**Photo 2: Aerial View of the KEMRI-CGHR and KEMRI/CDC Grounds at Kisian**





**Photo 3: Landscape View of the KEMRI-CGHR & KEMRI/CDC Grounds & Facilities**



**Photo 4: The KEMRI/CDC Science Wing**

The research facilities at Kisumu are colloquially referred to by members of KEMRI/CDC as the 'field station'. Hence I use this term whenever I refer to these grounds and their constituent buildings and laboratories. As noted above the field station is extensive and in addition to these research facilities there are two other smaller clinical research centres (CRC) maintained by KEMRI/CDC in Kisumu and Siaya. Both of these CRCs are located within the grounds of government hospitals. The Kisumu CRC located at Nyanza Provincial Hospital is

purely used for HIV-related research whereas the Siaya CRC at Siaya District Hospital (SDH) also houses patient care and support services for routine HIV+ clients. Research studies coordinated from these sites take place either within the CRCs, at peripheral health clinics, or in rural communities and, to a lesser extent in urban dwellings. The HDSS, described above, hosts the majority of research which is conducted by KEMRI/CDC although some malaria research also takes place in the highland areas of South Nyanza. These research areas share common characteristics in terms of health and demographic indicators: high infant mortality rates; high prevalence of malaria, HIV and Tuberculosis; and high levels of poverty (KEMRI/CDC Health and Demographic Surveillance System (HDSS), 2008, Central Bureau of Statistics Ministry of Health Kenya and ORC Macro, 2004, National AIDS/STI Control Programme (NAS COP), September 2009).

KEMRI/CDC employs a very large staff body of approximately 1000 people and in addition to these contracted employees KEMRI/CDC also works with casual workers such as Village Reporters (VRs) and volunteers such as community advisory board (CAB) members. The total number of contracted employees can fluctuate since employment depends on research projects which usually have a lifespan of 1-3 years. The majority of staff are employed on annually renewable contracts and these contracts are issued by KEMRI-CGHR. Hence all KEMRI/CDC employees are officially employed by KEMRI and subject to KEMRI supervision and pay scales. The largest group of staff are Field Workers (FWs), who are based in the rural and urban areas where health research is conducted. FWs only come to the field station for administrative visits or training. FWs mainly originate from the places where research is conducted and are usually secondary school leavers. The next main group of employees are those with technical and graduate training who perform clinical or laboratory duties, carry out quality management, coordinate studies, manage or analyse data, provide computer services, manage community liaison and communications, manage human resources or undertake other administrative duties. Most of this group are Kenyan nationals with a few exceptions where specific expertise is not available in the country. Some of these employees are based at the field station or CRCs, others work both at the field station and in the areas where research projects are taking place (i.e. the field), while others are based full-time in the field. Finally there are the research investigators and the senior scientists who direct the KEMRI/CDC research programme. This group comprises

international and national scientists who are employed by KEMRI or CDC or by means of consultancy agreements. In chapter 5 I elaborate on the KEMRI/CDC personnel structure in relation to my object of study.

The KEMRI/CDC research portfolio is far-reaching and includes epidemiological and clinical research in the fields of malaria, HIV, Tuberculosis, schistosomiasis, emerging infections, zoonotic infections and other infectious and viral diseases. Research findings are published in high profile journals and, in addition to core funding from CDC, the collaboration also attracts funding from organisations like the European and Developing Countries Trials Partnerships. KEMRI/CDC's extensive infrastructure including the HDSS and its access to areas where the target diseases for global health research are prevalent makes it an attractive trial site. This was the case for vaccine programmes like the Malaria Vaccine Initiative which brought together a range of pharmaceutical, philanthropic and government sponsors to accelerate the development of new vaccines.

### **The Vaccine Trial Case Studies**

The two vaccine trial case studies which formed the basis of my field work were a paediatric rotavirus vaccine trial (RVT) and a paediatric malaria vaccine trial (MVT). The RVT assessed the efficacy and safety of the oral rotavirus vaccine (Rotateq™) and determined immunogenicity in HIV + infants. The ongoing MVT is assessing the efficacy of the RTS,S/AS01 malaria vaccine candidate. Both trials involved randomisation and blinding of participants and study staff. The RVT was a placebo controlled trial, while infants in the control arms of the MVT receive either a meningococcal or rabies vaccine. All participants received a course of study vaccines, underwent relevant medical screening and home follow-up and some were required to provide either stool or blood samples.

The hospital and three of the peripheral health centres where the RVT and MVT took place are administered by the Kenyan Ministry of Public Health and the Ministry Medical Services. The other health centre is run by a faith-based non-governmental organisation under the supervision of the above ministries. SDH serves a population of 525000; the hospital has a capacity of 220 beds and is served by 3 specialists (Gynaecology, Surgery and

Ophthalmology) and 3 recently qualified medical officers who joined the hospital in the course of the MVT. A team of nurses, clinical officers, lab and x-ray technicians, support staff and a pharmacist support the medical colleagues. The health centres are usually manned by a couple of nurses and in some cases a clinical officer who can perform some medical duties. Two of the health centres offer basic laboratory services and some medicines are available at all the health centres. At these peripheral sites and the maternal child health (MCH) clinic at SDH, enrolling or outpatient participants are seen in rooms or tents that are adjacent to the regular clinical spaces. Hospitalised participants are admitted to the SDH paediatric ward where they are cared for by KEMRI/CDC staff alongside regular patients. KEMRI/CDC nurses, clinicians and medical officers, including a paediatrician, also assist with the care of general patients and KEMRI/CDC clinical officers support MCH and HIV patient care and support services.

From a scientific perspective the RVT and MVT represented significant promise for public health programmes seeking to reduce paediatric mortality and morbidity caused by malaria and rotavirus-related diarrhoeal disease. The efficacy and safety of the rotavirus vaccine (Rotateq™) has in fact already been confirmed (Armah et al., 2010), and this vaccine is now recommended for use in all national immunisation programmes by the WHO (WHO, 2009). Discussions are currently underway on how to support the inclusion of rotavirus vaccines into the Expanded Programme of Immunisation (EPI), so that children in all countries can benefit from rotavirus immunisation (WHO, 2011). Meanwhile the phase III trial of the RTS,S/AS01 malaria vaccine is ongoing. RTS,S/AS01 is the first vaccine candidate to progress to Phase III testing and preliminary results suggest it could prevent 50% of malaria attacks in children aged 5-17 months, and reduce the incidence of severe malaria by 40% in this age group (The RTSS Clinical Trials Partnership, 2011). These interim results have received considerable attention in the international media and given rise to much public hope and expectation (Briggs, 18th October 2011, Stobe, 18th October 2011, Ratemo, 19th October 2011). Malaria experts are expressing cautious optimism and drawing attention to the need to await the final analyses from this trial which are due in 2013/14 (White, 2011, LSHTM Malaria Centre, 2011). While the MVT is still ongoing, for the purposes of this thesis I will mostly refer to both trials in the past tense. This is both for ease of reference and to reflect

that my fieldwork and empirical data relate principally to a period in time between 2007 and 2009.

## **Conceptual & Theoretical Framework**

As a PhD student with a background in community health development in Haiti, clinical vaccine research and related applied qualitative research in the UK, the two vaccine trials allowed me to expand my understanding of community relations in an international context. My previous research had explored parental decision-making about trial participation, and parental and health professionals attitudes to the introduction of new vaccines (Chantler et al., 2007b, Chantler et al., 2006, Newton et al., 2006, Chantler et al., 2007a). In my PhD I wanted to build on this work and develop a richer theoretical and practical understanding of the use of anthropological methods in ethics research. This was made possible through a collaborative agreement between the Kenyan Medical Research Institute (KEMRI) and the London School of Hygiene and Tropical Medicine (LSHTM) established by my primary supervisor. At the time I was designing my PhD research my primary supervisor had commenced ethnographic fieldwork within the KEMRI/CDC collaborative research programme. Together with colleagues from KEMRI, the US Centres for Disease Control (CDC) and LSHTM, Dr Geissler is studying the 'ethos' and social life and everyday practices of medical research within international collaborations. This work is not focussed on the application of ethical and regulatory guidelines such as 'Good Clinical Practice' (International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use, 1996b); rather it seeks to understand the practice of medical research as a wider societal project. Core foci are how questions of social justice are voiced and addressed in practice. The 'ethos' of medical research in this work is understood to be *'the visions, and projects that orientate and direct the discourses and practices of different actors and groups, in different places, situations and periods'* (Geissler, 2011).

In approaching my study I started from the premise that the international research programme and the communities where the vaccine trials are taking place constitute a set of informal and formal social relations, a trial community (Geissler, 2011). My thesis looks at one particular segment of the KEMRI/CDC social network, namely the interaction between vaccine trial teams and the communities where my vaccine trial case studies took place.

These relations are my lens to understanding the practice of CE in this setting. Among the wider range of community relations, my focus has been relations between researchers and the following groups: community leaders who act as gatekeepers and collaborators; community representatives who act as intermediaries between researchers and community members; trial participants and their families; and community members. I explored the practice of CE from as many different angles as possible in order to understand the work that CE is meant to do, and the work it actually does, critically interrogating the assumptions and meanings behind this mode of intervention as well as its power and social effects. I traced the history of community relations, explored the perspectives of groups of people involved in CE and observed the social relations and interactions which characterise CE at the sites where the trials were conducted.

This thesis speaks primarily to debates in ethics around the nature and goals of CE, and the social value and practice of solidarity in bio-medical research conducted in resource-limited settings. It also seeks to contribute to the anthropology of clinical research by providing a rich description of the social construction of CE at KEMRI/CDC. This construction arises from a particular history, is shaped by the local context, and is informed by distinct ideas regarding who constitutes the 'community' and what 'engagement' with science and 'collaboration' in bio-medical research involve.

To complement this conceptual overview I now review pertinent literature which guided my initial thinking about CE and its relevance to research ethics, trials, health and development with due consideration to the cross cultural nature of my topic.

### **Ethical Challenges & Considerations of Context in International Research**

Particular ethical challenges can arise when important health research is carried out in resource-limited settings. A classic example of this is the 'standard of care debate' which was sparked by criticism of perinatal HIV transmission trials conducted by Western researchers in developing countries in the late 1990s. The inclusion of placebos in the HIV transmission trials and observation in viral transmission studies rather than the 'best' proven treatment available in developed countries ignited debate about what constitutes a

fair and reasonable standard of care for human research subjects in developing countries (Lurie and Wolfe, 1997, Quinn, 2000). Specific questions arose about whether 'best' current treatment should equate to what is locally available or instead what is available in the countries sponsoring the research. Strong arguments were made against moral relativism which could lead to breaches of ethical imperatives (i.e. ensuring that research subjects are not used as a means to an end), being justified by the scientific value of research and its potential to improve the care of future patients (Angell, 1997). Others associated criticism voiced in this debate with imperialistic attitudes and expressed concern about its threat to the continuation of medical research in less affluent countries (Gambia Government/Medical Research Council Joint Ethical Committee, 1998, Varmus and Satcher, 1997, Benatar, 1998).

Considerations of context were central to questions sparked in this debate, and philosophers and ethicists argued that the ambit of the debate over the standard of care was too narrow and failed to account for the reality of global health inequalities (Benatar and Singer, 2000). They drew attention to the arbitrariness of equating equal standards of medical care with the provision of particular drugs, and urged the scientific community to consider the broader context of care-giving and disparities in health research expenditure per capita between developed and developing countries. Inherent to their perspective is an understanding of ethics as moral reasoning rather than strict adherence to guidelines or similar prescriptions. This reasoning requires a distinction to be drawn between moral relativism and morally relevant issues of context. To support closer consideration of such factors, Benatar (2001) did however advocate for the introduction of new components to the Declaration of Helsinki. These components included: greater access to research for vulnerable groups in all countries; ensuring that research is relevant to research participants and their communities; encouraging the involvement of research participants in the planning and conduct of research; and linking research in developing countries with capacity-building in health-care. Some of these components have been integrated in subsequent revisions - for example, point 5 of the current declaration now states, that *'Populations that are underrepresented in medical research should be provided access to participation in research'* (World Medical Association, 2008). The wording of point 17 is also now more explicit about the need for research involving disadvantaged communities to be

responsive to the health needs of such communities and the benefits that such communities stand to gain from the results of research. These revisions and ethics review capacity-building reflect a move towards a more proactive research ethics which is intrinsically concerned about the inequities in global health.

Considerations of context require a greater appreciation of the different cultural lenses and frameworks of thinking which co-exist in the application of multinational collaborative research. The worldview and experience of privileged international researchers differs substantially from that of potential research participants from disadvantaged communities (Benatar, 2002); it also can differ from that of national colleagues with whom they are collaborating. National researchers may also not be able to identify fully with the social and economic realities which characterise trial participants' daily lives; however they will share more in common in terms of history and culture. Ugandan researchers have suggested that socio-economic inequalities between investigators and subjects can result in subjects feeling that they have no choice when asked to participate in research; they also consider how the legacy of colonialism evokes ethnic divisiveness between researchers and subjects (Loue et al., 1996).

Kleinman (1999) makes the case for the '*New Bioethics*' to adopt a two-pronged approach to ethics; one that combines the guidance of universal principles (e.g. Beauchamp and Childress' (2009) framework of four *prima facie*<sup>2</sup> principles) with proper accounting for local moral experience. From the perspective of an anthropologist he argues that bio-ethicists need an understanding of '*what is locally at stake*' in order to focus their ethical deliberation appropriately. This is particularly important where intrinsic inequities related to poverty, deprivation or other circumstances pre-exist in the places where research is proposed. Kleinman argues that principle-based formulations of justice used to review the ethics of trials can seem irrelevant if they do not account for pre-existing inequities. Like other authors (Benatar and Singer, 2000, Emanuel et al., 2004, Tangwa, 2004) Kleinman calls for a reframing of the relationship between universal principles and communitarian concerns in international health research.

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<sup>2</sup> Prima facie is understood by Beauchamp & Childress 2009 p. 198 to mean: 'no one principle of ethics should be viewed as the sole principle of ethics, nor as one that justifies or overrides all other principles'. The idea of prima facie obligations draws on the writings of the British moral philosopher W.D Ross (ROSS, W. D. 2002. *The right and the good*, Oxford, Clarendon Press



Benatar (2002) suggests that in order to make scientific and moral progress scientists have to do the following: be critical of the status of current knowledge, method and dogma; be willing to raise critical questions (e.g. about how research can ameliorate health conditions in resource-limited settings): acquire an understanding of their own base within a specific context; recognise the limitations of their own worldview; acknowledge that their insights are not always correct or better than those of others; and be willing to debate differences with an open and scholarly attitude. Adopting this approach may foster reciprocity, interdependence and candid discussion in international health research collaborations and help to ensure that studies reflect the health needs of the immediate beneficiaries (Benatar, 2002, Robertson, 1998).

The rhetoric of collaboration and partnership in multinational research can however also result in uncomfortable truths about unequal relationships being relegated to the background. This may be inadvertent or simply reflect the enormity of confronting these fundamental challenges head on. We may believe that health research should account for and respond to inequalities in global health, yet struggle to realise these ideals in practice. Farmer (2005) argues passionately against such apathy stating that more must be done to insert social justice into medical ethics. To remain credible bio-ethicists and researchers in particular must address key fundamental questions which formed the basis for a code of ethics (Tavistock Principles) drafted by professionals involved in health-care (Berwick et al., 2001, Tavistock Group, 1999, Farmer, 2005). The Tavistock code of ethics presents health-care as a human right, and hence Farmer argues (2005) (p.206): *'If access to health-care is considered a human right, who is considered human enough to have that right?'*

### **Collaborative Partnerships & Community Engagement**

Partnership has become a dominant paradigm within the field of global health and has been defined by Buse & Walt (Buse and Walt, 2000) as *'a collaborative relationship which transcends national boundaries and brings together at least three parties, among them a corporation (and/or industry association) and an intergovernmental organization, so as to achieve a shared health-creating goal on the basis of a mutually agreed division of labour (p.*

550)'. This definition captures the working relationships between sponsors, research organisations and governmental bodies in health research. However it does not include the beneficiaries of health interventions. I will follow up on this point in a subsequent paragraph; for now I want to consider the practice of partnership in global health and development, and outline some of the challenges and benefits.

Partners may share common goals but it is very likely that they will have diverse priorities and expectations. Diverse agendas - for example the prioritisation of gaining new knowledge over a desire to solve immediate problems or differing expectations concerning the nature of collaboration (on a continuum of perfunctory consultation to authentic partnership) have been documented in endeavours which seek to increase the participation of all players (Wallerstein, 1999, Huberman, 1991, Arnstein, 1969). The lines of accountability to the community or donors, organisational structures and cultures can also differ substantially between international partners, as can access to resources and professional support. The rhetoric of partnership can be both egalitarian and obscure. It is egalitarian in that it works from the premise that international partners have equal authority over and responsibility for projects. It is obscure since in practice the lines of duty are blurred, and it is difficult to tell who has more say over the direction of projects. This contrasts significantly from the autocratic colonial administration of the past in some African countries, where the hierarchy was unquestionably dominated by foreign officials. With the discourse of partnership Western researchers attempt to distance themselves from this unpalatable autocratic model, and yet the health research agenda is still primarily driven by sponsors, and research institutes based in the West-hence semi-colonial in nature (Costello and Zumla, 2000). There are exceptions e.g. the African Malaria Network Trust (AMANET) and some of the INDEPTH (The International Network for the Demographic Evaluation of Populations and Their Health in Developing Countries) Network sites, e.g. the Navrongo Demographic Surveillance Site. There the senior leadership is predominantly African. They have a defined research agenda, links with government ministries and have attracted funding from international bodies, e.g. the European Developing Countries Clinical Trials Partnership (EDCPT). This goes some way to reflect the partnership model described by Costello and Zumla (2000) which prioritises national capacity building, and seeks to reverse the 10/90 health research gap (i.e. the fact that developing countries bear 90% of the global disease burden but only 10% of health

research funding used to address these diseases). However even these institutes have to adapt their programmes to fit the funding priorities of Western agencies, and Kilama (2007) argues that more needs to be done to reverse the 10/90 gap.

Since the late 1990s increasing emphasis has been placed on CE in international health research as a means of promoting dialogue between researchers and people who live in the places where trials are taking place. In fact collaborative partnership between researchers and community representatives is cited by Emmanuel et al. (2004) as one of 8 principles of ethical research in developing countries. These authors who represent the US National Institutes of Health state that, at a minimum, proposed research should respect local values, culture and social practices and be regarded as important by community members. Accordingly community representatives' capacity should be augmented so that they can be involved in planning and overseeing research as community advocates. This focus on collaborative partnerships and CE in the arena of health research in developing countries was partly a response to the writings of Benatar and Singer (2000) and the increased attention being paid to the challenges involved in conducting medical research in developing countries. It also reflects the desire of the authors from the National Institutes of Health for pre-existing ethical constructs to become more responsive to community needs in a manner characterised by negotiation and agreement. In essence they were trying to insert more communitarian considerations into pre-existing western ethics models, which are predominately influenced by liberal philosophy and deontology and which prioritise individual autonomy.

The publication of this paper sparked much interest in what it means to engage a community in research; how do you do this, who should be engaged, by whom and how does this promote ethical practice. This is not to say that there had not previously been interest or an acknowledgement of the importance of collaborative partnerships or CE in international health research. To the contrary ongoing research from different parts of East Africa was highlighting the need for closer attention to be paid to community interactions in the application of health research. Questions of trust, consent, community acceptability, coercion and the role of community representative and local FWs were core themes in some of these publications (Molyneux et al., 2004, Mitchell et al., 2002, Molyneux et al., 2005a). However the term CE and associated practices acquired a new legitimacy in international

health research with the inclusion of CE explicitly in ethical frameworks (Emanuel et al., 2004).

CE in research is a very broad and complex term which can be difficult to define succinctly. Writing mainly for a national audience the US Centers for Disease and Prevention defined it in 1997 as *'the process of working collaboratively with groups of people who are affiliated by geographic proximity, special interests, or similar situations with respect to issues affecting their well-being'* (CDC/ATSDR Committee on Community Engagement, 1997). This definition is elaborated on in 9 principles (Appendix I, Doc. 1) as part of a first edition of an electronic resource about CE which has recently been updated (Clinical and Translational Science Awards Consortium Community Engagement Key Function Committee Task Force, 2011). Of particular interest to this thesis is the fact that these principles are not cited in documents which describe the framing of CE at KEMRI/CDC. I was also not introduced to these as part of my initial discussions with collaborators from the head office of CDC in Atlanta or at KEMRI/CDC. This may have been because these principles were primarily written for national programmes whereas CDC's main mission is domestic. This is apparent from the fact that promoting global health and related research was allocated only US\$340 million out of an overall budget of US\$10.8 billion in the financial year 2011 (Centers for Disease Control and Prevention, 2011).

Writing for an international audience involved in global health research Tindana et al. (2007) define CE as *'the process of working collaboratively with relevant partners who share common goals and interests'*. They believe that CE goes beyond notions of community participation and they draw attention to the importance of authentic partnerships, mutual respect, active inclusive participation, power sharing and equity and mutual benefits (Zakus and Lysack, 1998). It is evident that such thinking about CE is significantly influenced by ideas of what constitutes a 'community'. Hence it is essential to consider how the concept of 'community' is applied and defined in the overlapping fields of development, health and research.

### **'The Community' as a Concept in Development, Health & Research**

The term 'community' as applied to international health and medical research can refer to a geographical location and its inhabitants, a professional group (e.g. *'the scientific*

*community*'), or those at particular risk of certain diseases. At another level groups who share a belief system, culture or ethnicity are referred to as 'communities', as are economic and political alliances between countries, e.g. the EASCO (East African Common Services Organization) or the European Union. In essence the concept denotes a certain commonality – such as shared characteristics, similarities in beliefs, behaviour and attitude and/or living in a particular location. Communities are frequently characterised '*small-scale, having relative boundedness, strong affective ties, traditionalism, and face-to-face contact*' (Calhoun, 2002). This ideal typical view of a community can however fail to acknowledge external influences, internal heterogeneity and inherent power dynamics. Community boundaries have become more dynamic and difficult to delineate due to increased mobility, periodic migration for work or education and greater access to communication technologies. Inherent power dynamics are directly related to socio-economic factors such as gender, age, assets, family ties and education. Guijt & Shah (1998) argue that a naïve view of community as a harmonious and internally equitable collective can result in the opinions and priorities of those less able to voice themselves publicly being disregarded.

Weijer & Emanuel (2000) distinguish between 7 different types of communities and assess their cohesiveness by applying a defined set of characteristics. These characteristics are: common culture and traditions, canon of knowledge, and shared history; comprehensiveness of culture; health-related common culture; legitimate political authority; representative group/individuals; mechanism for priority-setting in health-care; geographic localization; common economy/shared resources; communication network; and self-identification as a community. They suggest that these characteristics can help ethicists to determine where and when specific ethical protections need to be applied in the conduct of bio-medical research. They also argue that the level and type of collaboration between communities, health-care staff and researchers is dependent on the existence of some of these characteristics.

The previous paragraphs focused on the conceptualisation of 'community' as an entity with which outsiders engage for a variety of reasons. The process of engagement itself can however also give rise to the formation of 'community' and the development of new relationships between internal and external agents. Medical anthropologists studying health and, in particular, research interventions have coined the term 'trial community' to capture

the broader social networks that are created in the planning and implementation of health research (Geissler and Molyneux, 2011). A 'trial community' encompasses not only the target population of the intended research but also those coordinating, conducting, funding and acting upon the research and its' findings. The shared sense of identity in this case is derived from the trial, and the shaping of 'community' results from the social relations constituted in the process of the trial. Research participants can derive significant social meaning and concrete benefits from belonging to a trial community (Leach and Fairhead, 2011). A paper about a malaria vaccine trial in the Gambia also depicts how relationships within a 'trial community' can contribute to the successful implementation of research (Geissler et al., 2008). FWs who were posted to the villages where the vaccine trial was taking place, developed kinship-like relationships with residents. Their interactions were guided by a concrete and relational form of ethics which the anthropologists differentiated from the abstract and vertical formal ethical principles that underwrite medical research. Rather than the one negating the other they argued that both kinds of ethics are needed to position trials between the networks of global science and its attendant legal frames on the one hand, and the concrete relations in which science is made on the other (Geissler et al., 2008, Fairhead et al., 2006a).

The 'community' as a political entity and an interface or a point of interaction was central to ideas about development and health in developing countries in the 1970s to 1980s (Chambers, 1983, Freire, 1972). While this focus on the recipients of care and their social worlds has been of great benefit there are drawbacks to this 'community-focused' approach. One of these is that, in their desire to reach out to the 'community', well-intentioned project implementers bypass (at times intentionally) governmental, political and medical actors that ought to mediate between citizens and larger health organisations. Thus, instead of operating through ministries and health-care facilities, projects access 'communities' directly. While this democratic impetus can sometimes be justified, direct access by outside power-holders to citizens also risks devaluing existing or possible structures of democratic representation. It is also important to remember that the concept of 'community' as a political entity is relatively new. In colonial times the 'community' as an entity would not have been recognised as a legitimate agent, it gained more recognition in the 1970s and 1980s. And although it has been partly replaced by reference to civil society

and citizenship during the 1990s and 2000s (Comaroff and Comaroff, 1999), communities and plans to involve them continue to feature prominently in health and development plans.

## **Community Participation in Health Programmes**

Community participation is one of the pillars of primary health care (PHC). PHC was a pivotal health policy adopted by WHO member states in 1978 following a conference held in Alma Ata (World Health Organisation, 1978). According to this, health planners and policy-makers expected community participation interventions to: increase the utilisation and sustainability of health services; achieve changes in health behaviours; and augment self-efficacy. Rifkin (1996) argues that community participation's failure to meet planners expectations can be traced back to a misguided paradigm; a paradigm which viewed community participation as a magic bullet for the resolution of problems rooted in health and political power structures. Within this paradigm community participation characteristically adopted one of 2 frameworks. Either a '*means to an end*' (i.e. an intervention that will succeed in meeting programme planners aims) or '*a means in itself*' (also termed the 'empowerment' approach, influenced by the Brazilian educationalist, Paulo Freire (1972)). Both the '*means to an end*' and the '*means in itself*' frameworks place immense pressure on mobilisation techniques to fulfil wide and varied agendas and are usually applied with mutual exclusivity. It is also important to note that what Freire (1972) was proposing was fundamental structural change by encouraging rural peasants to question the status quo. He voiced strong criticism about a 'banking style' approach to education which filled people's heads with factual knowledge but did not teach them to question or challenge political authority. His main work, 'Paedagogy of the Oppressed', was written based on his experiences of teaching literacy to adults in impoverished communities in the Northeast of Brazil. His writings are significantly influence by liberation theology and Marxist critical theory. Freire (1972) coined the popular educational and social concept 'conscientization' which derives from the Portuguese term 'conscientintização'. This is translated as critical consciousness; the process of developing a critical awareness of one's social reality through reflection and action. This philosophy is of relevance to community development and possibly to CE in health research. However in order for social change to be lasting there is also a need to work together with authorities to reshape social reality.

To apportion more realistic expectations to community participation in health Rifkin (1996) promotes the adoption of an iterative approach to community participation, informed by the rural development work of Chambers (1983, 1992) in the United Kingdom and Uphoff (1992) in the USA. Uphoff (1992) describes the need to move from an *'either-or'*, where the above-cited frameworks are applied in a mutually exclusive manner, to a *'both-and'* approach which lends more flexibility to working in contexts that may require both linear and non-linear solutions. Rifkin (1996) considers *'both-and'* to be a way of accommodating differing perspectives and achieving change in an iterative rather than a mechanistic manner. The *'both-and'* approach to community participation requires mutual respect between professionals and community. Professionals need to be non-judgemental and willing to engage in dialogue whilst guarding against a one-solution-fits-all approach, which fails to reflect the local context.

### **Practical Experiences of CE in International Health Research**

Those seeking to optimise methods of community participation or CE, as it is mainly referred to in international health research, will recognise the *'means to an end'* and *'a means in itself'* frameworks. In workshops opinions have differed about *'the feasibility and appropriate timing of consultation and priority setting in researcher civil society partnerships'* (Hankins, 2006) (p. W4); and target-driven and comprehensive strategies are reported in the literature (Diallo et al., 2005, Hantman and Gottemoeller, 2004).

Diallo (2005) describes a 6-step approach for obtaining community permission for research in cohesive, traditional societies. Similarly, Doumbo (2005) reiterates the importance of gaining permission from local leaders in research preparations. These *'means to an end'* strategies can achieve important groundwork, yet they may fail to capture other community members' perspectives. Molyneux (2005b) provides an illuminating quote from a Kenyan mother living in the Kilifi district (p.446): *'It is important for the fieldworkers to get permission from the chief to move around the area, but the chief cannot decide for my child. No way! Is he my husband....is he the one who has bought our unga flour?'* To promote open dialogue with diverse communities in the vicinity of the Kilifi research station, Marsh et al. (2008) developed a district level communication strategy. This work focused more on the



*'means in itself'* rather than the research goals (e.g. recruitment rates) and set out to build collaborative partnerships and strengthen ethical practices across a broader research programme.

Respectful relationships are core to the Emanuel et al. (2004) framework and their detailed reference to benchmarks for measuring good practice has initiated broader discussion about ethics and community. Overreliance on formal guidance, principles and a related 'tick box' mentality can stifle ethical reflection. Accordingly, Geissler et al. (2008) argue that *'research ethics should make space to unfold ethical relations'*; relations which either pre-exist or which develop in the implementation of public health trials. Drawing on ethnographic research into interactions between FWs and villages hosting vaccine research, they highlight the importance of attachment and familiarity versus detachment. Whilst attachment made it difficult for FWs to uphold certain trial restrictions (e.g., medication being available only to trial participants), the formation of social bonds allowed FWs' interactions to be guided by their *'ethical impulse'* or moral compass. Geissler et al. (2008) argue that, in order to achieve a correct balance, ethical guidance should be complemented by considerations arising out of interactions characterised by trust.

Trust is a relational notion which describes a voluntary relationship between two or more people (inter-personal trust) or between a person and an institution (institutional trust) (Gilson, 2003). Molyneux and colleagues demonstrate its importance with particular reference to consent and community perceptions of research (Molyneux et al., 2005a, Molyneux et al., 2005b). Their work emphasises the need to understand the social context and ensure that research teams incorporate both technical and inter-personal competence. The latter may be achieved by employing community-based assistants who are known and trusted by local residents (Gikonyo et al., 2008). It can also be achieved by collaborating with community representatives such as traditional authorities or members of community advisory boards (CABs) (Morin et al., 2003, Tindana et al., 2011). The selection of community representatives however raises questions about which people are best able to serve as spokespersons for the community and what the role of such representatives should be.

To maintain the integrity of individual consent processes and safeguard against a lack of voluntariness, incomplete disclosure and confusion about study terminology, Strauss (2001) proposed the use of CABs. These are bodies composed of community members who share a common history, symbols, language and culture with the study population. The proposed remit for CABs is to serve as a liaison between participants and researchers, by representing participants' concerns, protecting their rights and possibly facilitating the development of study materials. The demands of HIV+ activists' for input into setting the AIDS research agenda in the USA during the early 1990s was the original impetus for the formation of CABs. This CE mechanism is now commonly used in clinical research, albeit with widely differing outcomes. At one extreme CABs have halted trials due to concerns about the quality of evidence available on investigational products; at the other CAB members are noted to aligned themselves too closely with researchers and become less able to represent community views (Strauss et al., 2001).

Based on research conducted at 6 HIV prevention research sites, Morin et al. (2003) distinguish between 2 CAB models: a 'broad community' model which involves representation from a cross-section of the larger community, including government officials, educators, religious leaders, representatives of non-governmental organisations and people living with HIV/AIDS; and a 'population specific' model which reflects the needs of a particular at-risk group. In terms of application the 'broad community' model entails a more long-term view of a CAB's mission to respond to future research projects; whereas the population-specific model focuses on a specific protocol and its impact on study participants. Sustainability, the capacity of a CAB to contribute something of lasting value to its community, and compensation for CAB members have been commonly encountered problems. A CAB can function both as 'a means in itself' whilst also acting as a 'means to an end'; the ability of a CAB to build bridges between researchers and communities depends on its' mission, composition, training, remit and internal capacity.

## **Summary of the Literature Review**

Over the last decade, the concept of CE has made its way into international ethics guidelines and reports from organizations such as the Council for International Organisations of Medical Sciences (CIOMS) (2002), the US National Bioethics Advisory Commission and the UK's Nuffield Council on Bioethics (2002). This has resulted in calls to improve the processes of CE by conducting rigorous qualitative research to identify best practices (Newman, 2006). Current responses include the development and revision of UNAIDS and the AVAC (Global Aids Advocacy for HIV Prevention) guidelines on 'Good participatory practices in HIV prevention research' (UNAIDS and AVAC, 2011) and the development of frameworks for practice based on examples of CE (Bandewar et al., 2010, Tindana et al., 2007, Lavery et al., 2010, Nyika et al., 2010). Less research focuses on understanding how CE activities and related partnerships serve to address ethical challenges that emerge prior to and during the implementation of internationally sponsored bio-medical research. Hence, in my PhD research I attempt to redress this balance by describing and critically analysing the relationship between CE, ethics and the conduct of vaccine trials.

## **Outline of the Thesis**

This chapter has described the object of study and the context in which my ethnographic fieldwork was conducted. A detailed review of the key literature is given and my main findings are summarised to provide a road map for the rest of the thesis. In the next chapter I document the history of immunization and related research in Sub-Saharan Africa. In chapter 3 I describe my research design and present an account of my fieldwork. The subsequent chapters 4-11 contain my findings. Each findings chapter draws out key themes which I synthesise in chapter 12 in order to formulate an overarching conclusion.

Chapter 4 documents the history of community relations at KEMRI/CDC over the past 30 years and draws out central themes related to the rapid growth of the research programme, its' location and accountability, expressions of disconnect and the control and direction of interactions between researchers and community members. Chapter 5 provides a detailed overview of the contemporary framing of CE at KEMRI/CDC which suggests that CE is about

researchers reaching out to the community where trials take place. Much emphasis is placed on the transfer of information, transparency about the purpose of research and reaching out to as many people as possible. CE is viewed of as a learning process and something that has to be planned carefully to mitigate the influence of latent cultural idioms and related rumours. These rumours influence researchers' thinking about the local community and underscore boundaries and demarcations already drawn between the KEMRI/CDC and the place where trials take place.

In chapters 6-9 I present the social construction of CE among different people attached to the KEMRI/CDC trial community. I start by exploring the perspectives and experiences of those working for KEMRI/CDC and determine that the following aspects are key to understanding people's approach to CE: promoting a positive image; careful attention to the content of information shared with the media and general public; and demonstrating 'attachment' to the local community. In chapters 7 and 8 I shift my attention to community intermediaries that is those who connect researchers with community members. In chapter 7 we learn that VRs are employed casually to perform defined tasks for the HDSS and some trials. Their role is shaped by ambiguities related to their employment status and their dual accountability to researchers and their villages. VRs' position of being both with the community and with KEMRI/CDC emerges as advantageous for the conduct of research but clearly problematic in terms of exercising trust, balancing allegiances, adequately representing community views and responding to implicit and explicit expectations for material assistance. The concept of 'positioning' relating to people who travel across the imagined boundary between the community and KEMRI/CDC, which emerges in the chapter about VRs, gains further prominence in chapter 8 on CABs. CABs are voluntary bodies whose mandate at KEMRI/CDC is to foster partnership between researchers and the local community. In practice CAB members highly value their association with a modern and progressive project and assume the role of KEMRI/CDC patron-clients rather than community advocates. The influence of patronage is also apparent in chapter 9 which documents 'gatekeepers' experiences of CE. 'Gatekeepers' represent those who have the power to grant or withhold access to the setting in which one wants to conduct research. For KEMRI/CDC these people comprise those who hold positions of leadership within the government administration, the political leadership and the ministries of public health and

medical services. In chapter 9 I focus on the first two groups and key themes which emerge from this chapter are the importance of material engagements and meaningful and ongoing collaboration. Gatekeepers argue that you cannot apply a research agenda without accounting for inadequate health services and the poverty of most trial participants. For them the material expression of solidarity is central to CE and provides the basis for ongoing collaboration.

In the last two findings chapters I explore the diversity of community responses to the vaccine trial case studies, and the negotiations involved in hosting these trials in public health facilities. My analysis in chapter 10 shows that, as community members started to interact more closely with KEMRI/CDC, they began to lay aside hesitations and inherent suspicions which were heavily influenced by latent cultural idioms, such as 'blood stealing' rumours. Their attention became increasingly drawn to the benefits of trial participation and questions of exclusion began to dominate public concerns. In chapter 11 I describe how differences in health-care provision between research participants and routine patients are negotiated in the SDH general paediatric ward, where sick MVT participants are cared for by researchers. Whilst researchers and their MOH counterparts are in principle committed to the integration of research in places where general routine care is being provided, boundaries between scientific practice and general care are drawn in order to facilitate practice.

## **Conclusion**

The objective of this thesis is to study the understandings and practices of CE and the relationship between collaborative partnerships and ethics. The foci of my ethnographic enquiry are two paediatric vaccine trials being conducted by KEMRI/CDC in a rural area in Western Kenya. KEMRI/CDC is an international research collaboration which conducts public health research in impoverished communities with high levels of disease burden. The two paediatric vaccine trials represent significant promise in terms of medical advance and the *reduction of infant mortality rates across Africa*. The conduct of such clinical trials in resource-limited setting also gives rise to ethical challenges such as the voluntariness of trial

participation, informed consent, relative standards of care-giving, the social value of research and related distribution of benefits.

CE has been proposed as a means of addressing such ethical concerns. Hence increasingly attention is being paid to establishing ways of working with communities and their representatives in the implementation of bio-medical research. This interaction may also help promote a better understanding of contextual realities, and facilitate partnership between researchers and communities who are characterised by diverse experiences and worldviews. CE is therefore influenced by notions of relational ethics rather than the adherence to regulations and bio-ethical constructs, such as Beauchamp and Childress's four 'Principles of Biomedical Ethics' (2009): respect for autonomy; informed consent; non-maleficence/beneficence; and justice. At the same time social justice is presented as a core feature of CE by Emanuel et al. who present it as a way of minimising the risks of exploitation when trials take place in developing countries (Emanuel et al., 2004). In this thesis I critically analyse the basis of this argument by observing, discussing and documenting how the 'community' was engaged by KEMRI/CDC between 2007 and 2009 in the implementation of paediatric RVT and MVT.

## Chapter 2:

# The History of Immunization & Vaccine Research in Sub-Saharan Africa

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*'One tool we don't have yet today and that will be important in the future fight (against malaria) is a vaccine. A fully-effective vaccine is a wonderful thing. It's the simplest, most cost-effective way to save lives. The smallpox vaccine...led to the eradication of smallpox. The polio vaccine has gotten us quite close to the threshold of eradicating polio. Vaccines have slashed the number of deaths caused by diphtheria, measles, tetanus, and a host of other diseases. But developing a malaria vaccine has been a long and frustrating process. There have been certainly more failures than success, because this is a parasitic disease and the scientific complexity is significant. Today however we are closer than ever before to tackling that complexity.'*

**Bill Gates, 18<sup>th</sup> October 2011 Malaria Forum Address**

## Introduction

This chapter outlines the history of immunization and related research in Sub-Saharan Africa (SSA) with a particular focus on East Africa. I also refer to core milestones in immunization in other parts of the world as these intersect with the trajectory of immunisation practices in SSA. The primary aim of this historical narrative is to facilitate a grounded understanding of concerns which came to light in my field work and are reported in the findings chapters.

A paper on the advance of medical research in West Africa provides a historical framework of four periods namely: 'The pre-European period'; 'The colonial period'; 'The era of primary health care'; and 'The era of DNA' (Greenwood, 1998). The pre-European period includes early contact with European explorers and missionaries, referred to by Greenwood (1998) as the age of explorers, with the shift from this time to the colonial period occurring towards the end of the 19<sup>th</sup> century. Greenwood (1998) appears to use the term 'period' to denote more defined historic time spans that are set according to political events, whereas 'era' is applied to describe time frames which are influenced either by new thinking about

health services provision or technical developments. Drawing a specific timeline or boundary between the latter eras, 'The era of Primary Health Care (PHC)' and 'The era of DNA', is difficult, as one has not replaced the other.

In this chapter I use this framework lightly to trace developments in vaccine-related disease prevention from early variolation practices to colonial vaccination programmes, scaling up to the internationally organized and state controlled smallpox eradication campaign. The success of this campaign provided the impetus for the launch of the World Health Organization (WHO) Expanded Program of Immunization (EPI) in 1974. I have divided this chapter into two main sections with relevant sub-divisions. The first section concerns the milestones in immunization from the early 17<sup>th</sup> century to the development and implementation of the WHO EPI, and the second section considers current developments in immunization as we move into the era of DNA.

## **Milestones in Immunization**

Milestones in immunization (Text Box 1) are inextricably linked to human endeavours to prevent and cure smallpox. Earliest attempts included the practice of 'variolation' (from variola, a synonym for smallpox) which seeks to prevent smallpox by exposing healthy people to matter from the lesions caused by the disease, either by putting it under the skin, or by inserting powdered scabs from smallpox pustules into the nose. Variations of this practice have been observed across different cultures with earliest reports originating from China.



### **Text Box 1: Milestones in Immunization**

<b>429 BC:</b>	Thucydides notices smallpox survivors did not get re-infected
<b>900 AD:</b>	Chinese practise variolation
<b>1700s:</b>	Variolation reaches Turkey and rest of Europe
<b>1796:</b>	Edward Jenner: from variolation to vaccination
<b>1803:</b>	Royal Jennerian Institute founded in London, UK
<b>1870s:</b>	Violent opposition to vaccination in UK
<b>1880s:</b>	Louis Pasteur - sheep trials and rabies
<b>1890:</b>	Emil von Behring discovers basis of diphtheria and tetanus vaccines
<b>1920s:</b>	Diphtheria, tetanus, pertussis (whooping cough) and BCG (against tuberculosis) vaccines available
<b>1955:</b>	Polio immunization programme begins in UK
<b>1956:</b>	WHO launch global drive to eradicate smallpox
<b>1980:</b>	Smallpox eradicated

**Reference:** [http://www.immunisation.nhs.uk/About\\_Immunisation/History/Timeline](http://www.immunisation.nhs.uk/About_Immunisation/History/Timeline)

### **Variolation in Africa during the pre-European Period**

Herbert's (1975) survey of smallpox inoculation in Africa provides evidence that variolation was practised in scattered parts of Africa during the pre-European period. Geographically it was most extensively used in Western and Central Sudan, Ethiopia and Southern Africa. The survey draws on secondary sources, dated from the 18<sup>th</sup> century onwards, and describes a variation in techniques both in terms of the material used and the variolation site. A table (pp. 554-5) indicates that pus rather than scabs was the main choice of material and the arm the preferred site; other sites commonly referred to are the forehead, the space between the thumbs and fingers, legs, and the dorsal hand (Herbert, 1975). Sources cited also describe mixing the inoculating material with medicines, herbs and clay, honey or butter, animal deposit, or milky juice of a tree. According to the survey variolation was mainly used in response to outbreaks, epidemics or reports of disease in nearby areas.

The cultural and ritual significance of variolation in African contexts is discussed by the social historian Luise White (1997), who suggests that variolation was not only used for smallpox prevention but also applied to diseases and misfortunes that were not epidemic. She states that *'women and men were routinely variolated for everything from wealth and*

*fertility to protection from lion bites'* (White, 1997) (p.12). Thus a technique used to acquire immunity against smallpox is reinterpreted both as a means of warding off danger and obtaining status. Conceptually this suggests that people associated variolation with certain magical or spiritual qualities, as implied in Malian elders' descriptions of smallpox variolation scars as charms (Imperato, 1968) (p. 869). Indeed in Ethiopia hundreds of people were variolated during religious ceremonies which continued until the Ethiopian Emperor banned the practice in favour of vaccination in 1905.

Despite such bans, variolation was sustained, both amongst those who actively sought vaccination and those who resisted immunization. Variolation continued to be popular during epidemics and at the time of the WHO eradication campaign in the 1960s. There is evidence across the continent that variolation continued into the 20<sup>th</sup> century. Imperato (1968) for example provides a detailed account of the practice amongst the Songhai of Mali in 1967. He reports how people who had not been previously variolated or vaccinated were voluntarily inoculated with the use of a thorn or a bird plume. In both instances pus from a light case of smallpox was rubbed into superficial skin incisions. Whilst the attack rates reported did not indicate any advantage to variolation, Imperato (1968) reports no disadvantages either. He differentiates between superficial variolation techniques and those that caused more skin trauma (Imperato, 1968). The latter have been associated with causing severe smallpox disease rather than inferring immunity. This risk is referred to in reports of resistance to variolation in Kenya (Leakey, 1977), and is also the main reason why variolation was outlawed in England and Wales in 1840, at a time when Jennerian vaccination was gaining prominence (Stewart and Devlin, 2006).

## **The Birth of Vaccination**

The birth of vaccination is attributed to Edward Jenner (1749-1823), a family doctor, who became famous in 1798 when he published all of his research into smallpox (Jenner, 1798). In experiments Jenner tested the old folklore that '*people who catch cow pox don't get smallpox*'. Cow pox is a mild viral infection which causes weeping spots on cows' udders. Milk maids were exposed to this in their daily work. When a local dairy maid came to Jenner

with weeping spots on her hand, Jenner seized the opportunity to conduct his first experiment. He took James Phipps, his gardener's eight year old son, and made some scratches on his arms. Then he rubbed some of the material from one of the pocks on the milk maid's hand into these wounds. A few days later James became mildly ill with cowpox but was well again a week later. This demonstrated that cowpox could be transmitted from person to person as well as from cow to person. To test whether the cowpox exposure would protect the boy from smallpox Jenner variolated James. James did not develop smallpox on this occasion or on the many subsequent ones when his immunity was tested.

Jenner's technique of introducing material under the skin to produce prevention against disease has become known as vaccination. Whilst this technique bears some similarities with variolation there is a critical difference. In variolation matter that could cause disease in recipients is introduced, whereas in vaccination the material that is inserted will not cause the disease that the procedure seeks to prevent. Jenner used live cowpox to vaccinate against smallpox since it was a similar virus. Today a wide range of vaccines are used to prevent viral and bacterial diseases-attenuated live vaccines, inactivated vaccines and genetically engineered vaccines-and all such vaccines undergoing significant safety testing before they are administered to the general public.

Jenner's findings were translated into the main European languages of the time, and he travelled widely to demonstrate his technique and distribute cowpox serum. Whilst he awakened the interest of fellow scientists, some of whom confirmed his findings in their own experiments (Blake, 1957, Dixon, 1962), he also encountered a lot of opposition particularly in his home country (Stewart and Devlin, 2006).



**Figure 1: The *COW POCK* or the *Wonderful Effects of the New Inoculation!***  
 The Publications of y<sup>e</sup> Anti-Vaccine Society. Illustrated by James Gillray  
 (colour engraving) published June 12, 1802 by H. Humphrey, St. James's Street.

Compulsory vaccination in England was not introduced until 1853 at a time when liberal sentiments in support of freedom of choice were growing, and there was a lot of opposition to the Vaccination Acts both amongst the middle and working classes. For many the vaccination question became symbolic of uncompromising governmental intervention in the daily lives of individuals (Fenner et al., 1988a).

### **Vaccination in African during the Colonial Period**

Luise White's (1995) descriptions of colonial vaccination programmes in Africa also raise concerns about the incursion of outside authorities into people's lives. She writes '*...that distrust about vaccination had more to do with who was vaccinated by whom and whose body was being marked for what ends*'. The first smallpox vaccines were brought to Africa by missionaries whose good intentions were often applied zealously. The diaries of one missionary (Cook, 1945) describe a scenario that ensued at the time of a smallpox epidemic in Uganda in 1899. Two African boys were vaccinated with all that was left of vaccines brought from England and did not return to the clinic as instructed. So another young boy

with 'an obvious vaccination' mark was spotted at the market and dragged back to the clinic, where drops of lymph were extracted from him and used to vaccinate 6 others who were kept in observation. Eventually, by recursion to the arm to arm method, 800 people were vaccinated, in a manner resembling variolation with which local people may have been familiar. Cook, the missionary in question, never established how the young boy in the market came to have a vaccination mark in the first place. Instead he recounted how keen the population was to be vaccinated, so eager '*that they almost stormed the dispensary to get it*' (Cook, 1945).

White's (1995, 1997) analyses of the literature suggest that African responses to missionary and colonial vaccination were varied and polarised. Some accounts capture the enthusiasm related by Cook (1945), while others portray deep-seated distrust or even violent resistance. In 1929, for example, a European sanitation officer lost his hand in a struggle during plague vaccination campaigns in Uganda. Rumours were widespread, and repeatedly challenged the 'intentions' of immunization. Speculations that vaccines were designed to poison the population were rife; with one report cited African fears that Europeans had developed a vaccination that could cause 'bottled babies' or render women infertile (District Officials, 1939). Vaccination efforts were further undermined by reports of defective vaccines being responsible for the Kenyan smallpox epidemic in 1916 (Dawson, 1992), and the deaths of African soldiers stationed in the Belgian Congo in 1944 (Fetter, 1969). With this in mind it is not surprising to read about villagers who would flee from vaccinators (Patterson, 1981), and mothers from Nyasaland (present-day Malawi) who, even well into the 1950s, would hide their children to avoid vaccination (Vaughn, 1994).

Those targeted for immunisation were understandably suspicious of the process and the product. Colonial vaccination campaigns allowed for medical invasion into private lives and spaces (White, 1997), and employed methods such as hut burning, segregation and curtailment previously associated with forced labour and taxation (Vaughn, 1994). These kinds of campaigns that focused on vaccinating as many people as possible resulted in immunization being understood as a political tool of control and did little to promote the medical purpose of vaccination. Indeed, White (1997) argues that the power of the needle and dubious meanings attributed to vaccines meant that immunization hardly ever

impacted on African concepts of disease, contagion or prevention. This is not to say that Africans did not understand the theories of Western preventative medicine; rather these theories did not address their beliefs about the causation of disease, as illustrated in the following quote (Wilson, 1951 p. 313): *'It may be quite true that typhus is carried by lice, but who sent the infected lice and why did they bite one man and not another?* Ultimately the origins of disease were either ascribed to the will of a higher deity, or thought to be caused by divine punishment or personal malevolence. So whilst colonial authorities measured the success of smallpox campaigns in terms of numbers vaccinated, those vaccinated questioned how this could prevent disease caused by malevolence spite and anger (White, 1997).

During the colonial period vaccination was not routine in SSA, and inoculation campaigns were usually organised in response to an outbreak of smallpox or ad hoc when other vaccines became available. In 1951, for example, health officials in Nairobi vaccinated 43,000 people against typhoid and paratyphoid even though these diseases were rare in that city. The majority of the recipients did not associate the vaccine with protection against typhoid; instead they were seeking relief from a broad range of symptoms or expecting the vaccine to meet other needs such as safe travel. White (1997) suggests that people ascribed their own meanings to receiving the vaccine according to their personal needs; hence the actual medical use became immaterial for them.

A larger range of vaccines became available from the 1940s onwards according to staff<sup>3</sup> at the Kenyan Extended Programme of Immunisation (KEPI) offices in Nairobi. Their administration was prioritised in a way typical of the colonial medical system of the time, with vaccines being given to colonialists and their children first, then to their staff, and finally to Kenyan school children. Vaccines were also generally only available in major centres such as Nairobi or at Mission Hospitals. Around this time Kenya started to produce its own liquid smallpox vaccine at the Medical Research Laboratory in Nairobi. This meant that East African countries no longer solely relied on imports from the Lister Institute in England. Smallpox vaccines produced in England and Kenya shared a core limitation; they became sub-potent when exposed to ambient temperatures. Inadequate transportation and

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<sup>3</sup> I visited the KEPI offices on 30<sup>th</sup> October 2008 and talked to the Deputy Head and the Director. The latter had been involved in KEPI since 1980 and immunised children before that as a Medical Doctor.

storage facilities therefore raised questions about the effectiveness of the smallpox vaccination campaigns.

In the mid-1950s the World Health Organisation (WHO) began to develop a smallpox eradication campaign that changed the way in which immunization was organised. The campaign was initiated in the 1960s at a time when African nation states were in the throes of gaining independence and dealing with dwindling resources. Many nation states had become increasingly dependent on international support in the provision and prioritisation of medical care. Thus they found it difficult to refuse whatever medical programmes or vaccination campaigns donors requested. White (1997) describes the rise of sovereign agencies such as WHO and US Centers for Disease Control (CDC), and claims that these agencies prioritised global humanitarian concerns at the expense of local sovereignty and local humanitarian concerns. Her claims are valid to the extent that, amongst the many health problems faced by SSA countries in the early 1960s, smallpox was not a high priority. National involvement was also limited with the organisation of regional smallpox eradication campaigns being overseen by technical advisors contracted by WHO. Concerns with process have to be weighed however against the results of the campaign: the eradication of small pox in 1980.

### **Vaccination in the Era of Primary Health Care**

The East African smallpox eradication campaign in the late 1960s was an enormous encouragement to the global eradication programme. The productivity of staff led to the rapid and successful completion of the task at little cost and minimal effort (Fenner et al., 1988b). This example contributed to a realization that immunization could be delivered effectively through country-wide networks which could make it possible to protect all children against vaccine-preventable diseases. Hence in the spirit of the era of primary health care WHO launched its Expanded Programme of Immunization (EPI) in 1974.

EPI provides countries with guidance and support to improve vaccine delivery and to help make vaccines available for all children. The original EPI vaccines were the Bacille Camille Guerette vaccine against Tuberculosis, the diphtheria-tetanus-pertussis vaccine and oral polio and measles vaccines. This standardized immunization schedule was introduced in

1984 based on immunological data. In a span of 30 years EPI achieved a substantial increase in childhood immunization rates from 5% to 80%. However in 2003 it was estimated that, worldwide, 27 million children still remain unimmunized (WHO and UNICEF, 2005). Today EPI has a decentralized management structure with national programmes responsible for improving access to traditional EPI antigens and introducing new vaccines.

EPI in Kenya was formalised in 1980 when it was launched by the then Ministry of Health (MOH) as an official strategy based within the Division of Family Health. Despite government endorsement this 2-3 man operation, referred to as KEPI (Kenyan Expanded Programme of Immunization), relied heavily on funding from donors, UNICEF, SIDA and DANIDA. In 1984 an agreement was drawn up between DANIDA and the Government of Kenya (GOK) stated that DANIDA would run the programme and gradually hand back responsibility to the GOK within a specific timeframe. Under DANIDA management KEPI had three goals: capacity building, increasing the range of facilities, and consolidation. In the first instance health workers were trained and capacity built up across the country to allow the programme to extend beyond Nairobi to the other Provinces. This investment led to good vaccination coverage rates across the country. Setbacks occurred however in the 1990s when the GOK, under President Moi, began to renege on its obligations linked to the phasing out of DANIDA funding. DANIDA finally withdrew all support early in 2000 and KEPI was left with no stocks and no plan. The GOK was forced to take action and it injected 40 million Ksh (approximately US \$ 6 million at that time) into the programme. This cash enabled KEPI to continue vaccinating against polio and tuberculosis but they required the support of other donors for the provision of other antigens. It also had to negotiate with the Department of Health to meet running costs such as the provision of gas to maintain the cold chain. Parents were even asked to *bring their own syringes and needles if they wanted their children to be immunized.*

In 2001 the Global Alliance Vaccine Initiative (GAVI) supported the introduction of a new pentavalent vaccine that provided protection against two additional diseases, Haemophilus Influenzae type b and Hepatitis B. Initial excitement waned when health facility staff realized that the *auto-disposable syringes provided were reserved for the administration of the new vaccine.* This led to more confusion amongst parents; why were there syringes for some vaccines and not for others? It finally reached a point when health workers said that



this amounted to discrimination, and started to use the auto-disposable syringes for everything and anybody. GAVI was informed and as a result agreed to provide a 3 year grant for all vaccines and equipment. This grant came to an end in 2004 when the new government headed by President Kibaki introduced the first expanded budget on immunization.

Today KEPI has a larger staff body and works closely with the Ministry of Public Health and Sanitation to implement their programme across the country. It has witnessed a lot of achievements most remarkably the control of measles, over the past 20 years. In the 1980s there were measles wards in hospitals; today deaths due to measles are rare and the incidence of sequelae, such as blindness, has decreased dramatically. Diphtheria is also very rare although Kenya has not yet been certified as diphtheria free. Random cases of tetanus still occur and pertussis is seen sporadically. Tuberculosis remains a major challenge and KEPI also plans to target additional childhood diseases in the near future. 'The race for improved vaccines in battle against pneumonia is on' writes Mwangi (2010 ) in a Daily Nation news article published on 5<sup>th</sup> December 2010. Eleven years after the pneumococcal conjugate vaccine (PCV-10) was licensed and made widely available in North America, Europe and South Africa, the Ministry of Public Health acted to introduce the vaccine across Kenya from January 2011. This initiative was sponsored by GAVI and the Advanced Market Commitment (AMC) Funds which have pledged to lower the cost of PCV-10 from KSh 4000 (US \$ 53) to KSh 12 (US \$ 0.16) based on the success of roll out studies conducted by the KEMRI-Wellcome Trust in Kilifi and Thika districts (Kamadi, 2010).

This story of the KEPI demonstrates how national immunization programmes in resource-limited settings continue to rely heavily on external support. The main decisions about the priorities of the programme are still taken at an international level. This is not to say that the prevention of childhood disease is not a national priority; rather, it shows how access to new vaccines and changes to national policy depend heavily on support from international sponsors, philanthropists and global alliances.

## **Current Developments in Immunization: Moving into the Era of DNA**

Although I have situated the launch of the EPI within the era of primary health care, developments in vaccine technology have moved this programme into the era of DNA. Currently the era of DNA is most prominent in vaccine research and new candidate vaccines are being tested in phase 1-4 trials across SSA. This testing and the subsequent inclusion of proven vaccines into national immunization programmes will result in wider public debate about the risks and potential benefits of new generations of vaccines. Public debate can take on many mantles from rumours, press coverage of different perspectives, conferences and advocacy group meetings, to forums which promote dialogue between health professionals and lay persons.

In the 20<sup>th</sup> century unforeseen severe side effects have resulted in the withdrawal of certain vaccines and led to vaccination scares. A notable example occurred when a whole cell pertussis vaccine used in the UK in the 1970s resulted in an increase in febrile convulsions post-immunization. More recently Rotashield™, a live attenuated rotavirus vaccine approved by the FDA in 1998, was removed from the market little more than a year later. Post-licensure surveillance reported an increase in intussusception of the bowel following vaccination with Rotashield™. Others scares could be more accurately described as anti-vaccination rumours, since their supporting arguments and related evidence have not been accepted by the scientific community. In Western Europe, a prime example is widespread speculation about the association of the MMR vaccine with autism and inflammatory bowel disease (Dyer, 2010, Greenhalgh, 2010)

In SSA different rumours have been successful in capturing the imagination of the populace and the media. For example claims that polio vaccine is laced with HIV virus, or may have introduced HIV to Africa (Hooper, 1999), and fears that some immunizations are used to control fertility are common across the sub-continent and have led to resistance against vaccination (UNICEF, 2001, Feldman-Savelsberg et al., 2000, Milstien et al., 1995, Pascal, 1991, Jegede, 2007). Such scares and controversies are often the result of misunderstandings or mistrust in scientists' motivations, state information and official reasons for seeking to control public health. This has led authorities to stress the need for

both improved social mobilization built on stronger community relationships and better information strategies with consistent and clear messages (UNICEF, 2001) (pp 65-67). Laudable in principle and practice, these recommendations may go some way towards reducing vaccine anxieties in SSA. However controversies like Hooper's (1999) Origin of AIDS Theory are not easy to dispute or debunk by forensic epidemiological argument alone. A social scientist quoted in a news article about a Royal Society meeting on the origin of the AIDS virus correctly surmised that controversial theories will continue to capture the imagination of people (Cohen, 2000). This was my experience in a conversation with two professional women from Kenya and Ghana, who are both actively involved in aid and development in their countries. They expressed a lot of suspicion about scientists' role in the origin of HIV and surreptitious testing of drugs which they believe continues to happen today despite improved national ethics review capacity.

### **Vaccination Discourse**

Official communication about vaccination in SSA tends to rely on the packaging and delivery of pre-defined messages to the populace. Messages are disseminated in the form of posters, leaflets, media clips or by healthcare workers. Little attention has been paid to the importance of developing a vaccine discourse that builds on local understandings, is informed by contextual factors and promotes dialogue.

In the absence of meaningful dialogue it is not surprising that anti-vaccination rumours have abounded in SSA and, in one incidence resulted in a regional boycott of a Polio vaccination campaign (Jegade, 2007). In post-colonial SSA core arguments against vaccination have been of a religious or political nature with rumours mainly occurring in response to internationally-sponsored eradication campaigns involving oral polio and injectable tetanus vaccines (UNICEF, 2001). In Tanzania, Cameroon, Uganda, Kenya and Nigeria rumours have claimed that these vaccines contain anti-fertility drugs that would sterilize women and children, with East Africans also voicing fears that oral polio vaccines used in campaigns were laced with HIV (UNICEF, 2001, Feldman-Savelsberg et al., 2000, Jegede, 2007, Milstien et al., 1995). These rumours suggest that vaccination campaigns are interpreted as governmental or 'Western' plots to subdue certain population groups (Jegade, 2007,

Feldman-Savelsberg et al., 2000, UNICEF, 2001). Indeed the 2003-2004 polio vaccine boycott in the predominantly Muslim northern Nigerian states was resolved in part when Muslim leaders demanded that an Indonesian company become the new supplier for polio vaccine (Jegele, 2007). In the political climate of post 9/11 Nigeria's Muslim leaders were only willing to entrust fellow Muslims with the testing and production of what had become a controversial vaccine.

Considering the history of anti-vaccination rumours in West Africa Leach and Fairhead (2005) suggest that they take root where: a) top-down, coercive campaign-type approaches are used; b) where technological and management practices intersect with cultural conceptions that make anxieties 'make sense' (i.e. targeting certain population groups, like young girls); c) where the motivations of vaccine-providing institutions are interpreted within the context of local, national or international political tensions; and d) where rumours are spread by influential individuals or media networks. Rumours are therefore not simply illegitimate misconceptions that can be overcome by providing 'accurate' information (Leach and Fairhead, 2005). Instead they are complex expressions of people's understandings or misunderstandings of events within a particular time and context; a 'collective consciousness' which is informed by past experience and collective memory (Geissler et al., 2008). A tetanus vaccination campaign that took place in Cameroon in 1990 illustrates how collective memories of French colonial medical efforts to wipe out sleeping sickness and smallpox were highly influential. The colonial military-run medical services had targeted these diseases through mass forced vaccinations and treatment regimes (Feldman-Savelsberg et al., 2000). Memories of these events and associated collective consciousness are thought to have contributed to the terror witnessed in response to the 1990 internationally supported and state run tetanus campaign (Feldman-Savelsberg et al., 2000).

Rumours can be viewed as a form of individual and collective information-seeking when a formal information gap exists, either due to incomplete information or mistrust of the information sources (Rosnow and Fine, 1976). Miscommunication does not however explain the origin, content or ramifications of rumours, since the roots of these are found in 'contextual features' such as social structure and political climate. Typically rumours emerge in an atmosphere of general anxiety, credulity and ambiguity (Rosnow, 1988), or when people are seeking to explain relationships between groups having unequal political,

economic or social power (Turner, 1993). The latter in particular is true of blood-stealing rumours that have been documented across SSA, which in the past have been associated with colonial healthcare or more recently with internationally sponsored medical research (Geissler and Pool, 2006a, White, 2000).

Vaccination rumours can be interpreted as a particular local engagement with global and national projects. As such they must be taken seriously and responded to in a way that addresses underlying political and cultural dynamics which are often the root causes. Appropriate responses should aim to mitigate any negative consequences, and equally importantly create open forums in which dialogue can take place. In chapters 5 and 10 I return to the topic of rumour, and explore in detail the nature, genesis and implications of rumours which circulated during the course of my fieldwork.

### **The Social Shaping of Immunization**

According to Streefland et al (1999) responses to immunization and vaccination demand are thought to be shaped by 'local vaccination cultures', defined as '*prevailing beliefs about disease aetiology, ideas about the potency and efficacy of modern medicine, and views about the need for preventive health measures within a specific socio-cultural context*' (p.1706). These are shared notions which emerge when community members exchange accounts of their vaccination experiences and their interactions with healthcare providers. Vaccination encounters themselves are also influenced by contextual factors such as the physical location (dispensary, health centre or hospital) and organizational structure of a specific immunization programme. Streefland (1999) distinguishes between routine vaccination and campaign vaccination, describing the former as familiar in terms of location, timing, personnel, language and technology and the latter as unfamiliar in all those elements. He suggests that campaign conditions make people reflect on basic questions regarding vaccination and that the introduction of a new vaccine in routine conditions can alter normal responses to immunization.

In Kenya today, most immunizations are integrated into the regular healthcare services. Routine KEPI vaccines are administered at dispensaries, health centres and hospitals by

nurses, clinical officers and doctors, who also attend to other healthcare needs. In contrast KEPI campaigns, usually part of international eradication programmes, are held as separate events and referred to as National Immunization Days. Kenya's experience of these programmes, particularly the Polio campaigns in 1996 which were a source of great controversy, confirms Streefland's view that campaign conditions raise difficult questions about the purpose and intention of vaccination (UNICEF, 2001).

In relation to social demand for vaccination recent research from the Gambia suggests that this is not typically based on general trust in biomedicine or disease-specific knowledge. Instead mothers have a 'culturally-grounded active demand' (Leach and Fairhead, 2005). This demand is based on a set of concepts of infant health and vaccine actions in: a) preventing disease in general; b) 'chasing out' illness from a child's body; c) attenuating disease effects; and d) promoting strength and weight. Nichter (1995) describes similar cultural understandings of vaccinations where demand is either triggered by a perception that all vaccinations are good for infants' growth or health or by a marked sense of vulnerability to serious illness that may or may not be protected against with the vaccine sought. In the Gambia vaccination is also understood as complementing everyday and traditional practices performed to protect health (Leach and Fairhead, 2005). The mother attends to the child's basic daily needs, comports herself in a moral manner and believes that immunization, traditional medicines and 'talismen' can work together to promote her child's health.

These findings illustrate the importance of developing an approach to vaccination education and service provision that builds on local conceptual frameworks rather than delivering 'top-down' messages that rely on political leverage and prodding of health staff to secure compliance (Leach and Fairhead, 2005, Nichter, 1995).

### **Vaccine Research: A Growing Agenda**

Over the past two decades an increasing amount of vaccine research has taken place in SSA and this is likely to increase as we move more firmly into the era of DNA. Much of this research takes place in large research centres that have been developed as a result of collaborations between national and international research institutes. These research

centres, equipped with state-of-the-art technology and comfortable working environments, are often situated in impoverished regions. This juxtaposition that focuses attention on the global economic inequalities against the backdrop against which transnational research throughout most of Africa is now being conducted (Fairhead et al., 2006b). These inequalities are interpreted in the transactional logic that those who are targeted for participation apply when deciding for or against participation. Fairhead, Leach and Small (2006a) describe how a decision to take part in a trial run by the Medical Research Council (MRC) in the Gambia, can involve balancing the benefit of free medical care against the perceived danger of one's child being drained of blood for sale to Europe. In the context of medical research blood-stealing rumours have been interpreted in contrasting manners. Biomedical scientists usually understand them as misconceptions that can be dispelled by demystification of science and visits to laboratories. Historians and anthropologists on the other hand have interpreted them as an indigenous idiom of resistance to colonial oppression or millennial capitalism (Fairhead et al., 2006b p.3). Research findings from the Gambia suggest a more pragmatic interpretation in which blood is seen to be central to the political economy of the global medical and medical research industry and viewed by research participants as a commodity that can be used for reasonable transactions (Fairhead et al., 2006b). Rather than simply focusing on the demystification of science, Fairhead et al (2006b p.14) argue that medical researchers need to acknowledge such thinking and related socio-economic relationships in their encounters with community members.

Willingness to participate in trials, including vaccine trials, is shaped by the historical legacy of research institutions undertaking such research. Fairhead et al, (2006a p. 104), for example, found that knowledge of the aims of a particular study was less significant to people's decisions about participation than their longer term experiences of the MRC as an institution. Of interest here too is the fact that the MRC was also often mistaken for a healthcare provider raising a further question about whether vaccine research is perceived as 'routine' rather than 'campaign', i.e. out of the ordinary.

## **Conclusion**

The profile of immunization and vaccine research is set to grow in SSA over the coming decades particularly with new developments in the search for a malaria vaccine, HIV vaccine and improved Tuberculosis vaccines. DNA technology has also opened the way to the development of new generations of vaccines, indicating that the era of DNA could be one of promise and will involve challenges for SSA. This review of the history of immunisation and vaccine research in SSA and elsewhere suggests that the intentions and motivations of scientists, governments and health policymakers will be questioned. The provision of accurate information alone will not suffice to address suspicions; instead more attention will need to be paid to understanding the 'collective consciousness' which shapes public opinion in regard to immunisation and vaccine research.



## Chapter 3: Research Design, Fieldwork and Analysis

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*'The only way to make sense out of a phenomenon and its context is to plunge into it, move with it, and join the dance.'*

*Adaptation of a quote by Alan Watts (2011 p.177)*

### Introduction

The purpose of this chapter is to describe my research design and provide a detailed account of my fieldwork. In the first section I state the purpose of my research and give reasons for my choice of Ethnography as a study methodology. I outline the main features of an ethnographic approach paying particular attention to the practice of participant observation. The way in which an ethnographer enters into and operates within the 'field' is of primary importance in this type of research. Accordingly, I then provide an appropriately detailed account of my fieldwork, with reference to how I got in, stayed in and pulled away from the place which was the focus of my ethnography.

My ethnographic fieldwork took place in a rural area in Western Kenya, where KEMRI/CDC was implementing paediatric vaccine research. In chapter 1 I introduce the KEMRI/CDC research programme and described the geographic and socio-economic context in which the RVT and a malaria vaccine trial (MVT) took place. Hence in this chapter I concentrate on the way in which I studied these trials, how I collected data, who I worked with and how I analysed the data. Overall I spent two and a half years in the 'field' which, for me, represented the KEMRI/CDC research programme in Western Kenya.

## Research Design

The conceptual and theoretical framework outlined in chapter 1, a scoping visit to the KEMRI/CDC research programme in February 2007, and ongoing discussions with supervisors, academic peers and co-investigators at KEMRI/CDC informed the development of my research design. The premise on which this thesis is built is that the KEMRI/CDC research programme and the communities in which the vaccine trials are taking place constitute a set of informal and formal social relations, a 'trial community' (Geissler, 2011). These relations are my lens to understanding the practice of CE in this setting. From the spectrum of trial community relations I focus on those between researchers and the following groups: community leaders who act as gatekeepers and collaborators; community representatives who act as intermediaries between researchers and community members; trial participants and their families; and community members. I explore the practice of CE from as many different angles as possible in order to understand the work that CE is meant to do, and the work that it actually does, critically interrogating the assumptions and meanings behind this mode of intervention as well as its power and social effects.

To observe and record the relevant interactions and relate them to ethical debates I chose to conduct ethnographic fieldwork. In bio-ethics there is a growing awareness of the value of ethnography to elucidate the moral dilemmas encountered in the social worlds in which bio-medical technologies are conceived, tested and applied (Marshall and Koenig, 2001). Sociologists, anthropologists and philosophers concur that ethnography can represent a *valid conduit for understanding the lived moral experiences of social actors, who can be both subjects and objects of ethical deliberation* (Parker, 2007, Kleinman, 1999, DeVries, 1995).

Broadly speaking this piece of research asks two interlinked questions: how does CE work in practice, and in what ways does CE support ethical practice vaccine research in resource-limited settings? My literature review suggests that the normative 'ought' of CE is established. What is less clear is what CE means in practice and whether CE and related collaborative partnerships can be framed as a principle of ethical practice. How do engagements between researchers and community representatives, community members

and trial participants support decision-making about the conduct of vaccine trials, facilitate deliberation on fundamental concerns and help to identify ways of addressing or negotiating emerging challenges? Accordingly I started this piece of ethnographic research with the following research questions and study objectives.

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## **Research Questions**

How does the KEMRI/CDC Kisumu field station engage with the 'community' when preparing for and implementing multi-site vaccine trials in resource poor settings, and in what ways do these community engagement activities support 'ethical practice' in vaccine research?

## **Study Objectives**

1. To review the way community engagement is planned and practised over the course of vaccine trial preparations and implementation.
  2. To explore community representatives' and staff members' understanding and use of the concepts 'community', 'community engagement' and 'ethical practice' in vaccine research.
  3. To observe vaccine trial related community engagement activities and document community concerns that are raised during these events.
  4. To describe the way that community concerns and ethical challenges emerge during community engagement events and how they are negotiated and addressed.
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## Methodology

To frame my ethnographic work I draw on Kleinman's (1999 p. 5) definition of ethnography which conveys critical points about presence, distance and the tensions of balancing insider ('emic') and outsider ('etic') obligations and perspectives. This definition captures some of my experiences which I recount in the fieldwork section of this chapter.

*'Ethnography is a method of knowledge production by which the ethnographer enters into the ordinary, everyday space of moral processes. The ethnographer, no matter how successful she is in participant observation, either is or becomes an outsider - even if she begins as an indigenous member of the community she studies. She feels the tug of local obligations and the push of local practices, but for all that she is never so completely absorbed by what is most at stake for community members that their world of experience is entirely hers.'*

Participant observation, also referred to as presence, is the hallmark of ethnographic fieldwork. It implies that the researcher joins the group (in my case the KEMRI/CDC collaboration) which is to be studied, participates in its activities, and spends extended periods of time in this place. This raises some questions about the balance of involvement in the phenomena being studied. Bernard (2011p. 260-261) distinguishes between 2 different types of participant observers; the 'participating observer', and the 'observer participant'. Participating observers immerse themselves in the study setting but are not actively involved in all activities. Observing participants on the other hand may assume certain responsibilities in order to be able to gain access to areas and situations that would be otherwise out of bounds. Fluidity exists between these stances of participant observation and ethnographers can use different types of observation at different points of time. Both of these differing stances had a bearing on my research and I comment on this in my fieldwork account.

Fetterman (1998 p.31) describes the participant observer as a human instrument who, armed with a research question/problem, a theory of social interaction or behaviour, and a variety of conceptual guidelines in mind, strides into a culture or social situation to explore its terrain and to collect and analyse data. Whilst the human instrument relying on all its senses, thoughts and feelings can be a highly sensitive and perceptive data collection tool,

at the same time the human instrument can also be open to subjectivity and lose its bearings in unfamiliar behaviours and situations. By understanding one's position, working with a group of trusted researchers who are accustomed with the research setting, and checking the validity of findings and observations the researcher can guard against subjectivity.

The influence of the participant observer on the setting and resulting actions needs to be recognised and thus ethnography has been described as 'performative' (Fabian, 1990). Ethnographers do not apply neutral methods in the collection of data; rather they seek to observe circumstances and conditions in which data is enacted and can be talked about. Whether and how the presence and the length of stay of a participant observer in the place of study distorts the data collection are valid questions, which are captured in the following quotation by Tedlock (1983 p.287).

*'The more a fieldworker [or ethnographer] knows and is known, the less that fieldworker can avoid joining the action. The other side of this is that the less a fieldworker knows and is known, the greater will be that fieldworker's inability to interpret the actions of others, whether those actions take him into account or not.'*

Ethnographers try to be reflexive about how their presence can influence social processes, how they balance observation and data collection with involvement in the phenomena they are studying, and how their interpretations can be shaped by the 'cultural lenses' through which they perceive and make assumptions about the world. The value of being transparent is stressed by Pool and Geissler (2006 p. 287) who argue that: *'all social knowledge is positional and shaped by the observers' point of view, and there is no independent vantage point from which to view, neutrally, a given society'*. In my fieldwork I attempted to practice reflexivity, and I also complemented my perspective by working with three Kenyan research assistants, two of whom were resident in and originated from the area where I conducted my fieldwork. The next section provides an account of my fieldwork and methods. I differentiate between 3 stages of fieldwork and consider how my position as an 'observer participant', 'participant observer' and a 'semi-removed analyst' framed my enquiry.

## Fieldwork & Methods

To provide a descriptive and critical analysis of the substance and meaning of CE I conducted ethnographic fieldwork in Western Kenya from June 2007 to December 2009. My fieldwork focussed on the places of coordination and sites of implementation of paediatric rotavirus and malaria vaccine trials. I spent time in the KEMRI/CDC field station and in the rural area where CE and trial-related activities took place. I interviewed KEMRI/CDC staff and accompanied KEMRI/CDC members of the vaccine trial teams as they conducted CE and trial related activities. This gave me unique opportunity to study the trials from within the culture of the organisation. I also interviewed and spent time with community intermediaries, community members and parents of vaccine trial participants. This meant that I was able to describe the institutional structures and official representations of CE, and explore the experiences and understandings of CE both from the perspectives of those enacting it and those exposed to it.

Participant observation formed the basis for my data collection and guided my sampling and the topics I explored in informal conversations, semi-structured interviews (SSIs) and focus group discussions (FGDs). The strength of combining observation with interviews is that one can triangulate the data and compare what people say with what they do. My approach to data collection was inductive and SSIs and FGDs tended to follow participant observations. For example, where possible I tried to interview parents/guardians of vaccine trial participants who had allowed me to observe the consent process they underwent before being enrolled on the trial.

I used purposive sampling to identify information-rich cases to take part in interviews and FGDs. According to Silverman (2005) purposive sampling allows researchers to select cases that demonstrate particular features or processes whilst also requiring them to think carefully about the parameters of the population they are studying (p.129). I took care to achieve maximum variation according to age, gender and residential area in order to achieve a fair representation of outcomes. I also used theoretical sampling to test emerging ideas or theories e.g. paternal hesitation about infant participation in research. Theoretical sampling is an extension of purposive sampling and has been defined as *'the process of data collection for generating theory whereby the analyst jointly collects, codes, and analyzes his*

*data and decides what data to collect next and where to find them, in order to develop his theory as it emerges'* (Glaser and Strauss, 1968 p. 45).

My study participants included people from four different groups which I describe below. When quoting members of these groups in the thesis I use the following acronyms followed by the participants' number: Research Staff (RS, 01), Community Representative (CR, 02), RVT Participant (RP, 03), MVT Participant (MP, 04), Community Member (CM, 05). Study participants either took part in a SSI or a FGD and in some instances I interviewed a few people on more than one occasion. This was the case for 6 researchers and 7 VRs. Table 1 provides the number of participants in each group, the overall sample size and the number of FGDs and SSIs held with each group. More details about study participants including their background information, gender and age range and the dates when interviews of FGDs were held can be found in Appendix I Doc. 2.

### **Groups Participating in this Ethnographic Study**

- I. KEMRI/CDC Staff Members:** Senior Scientists, Trial Investigators, Community Liaison Staff, Communications Team, Technical Staff, FWs
- II. Community Representatives:** VRs, CAB members, Government & Political Gatekeepers, Health Facility Partners
- III. Parents/Guardians of Vaccine Trial Participants:** Mothers and a few fathers who had enrolled their children in the RVT or the MVT.
- IV. Community Members:** Religious leaders, Herbal medicine practitioners, Young professionals (working with community based organisations), Parents/guardians of children not taking part in the vaccine trials

**Table 1: Number of Study Participants, SSIs & FGDs**

Group	No. of Participants	No. of SSIs			No. of FGDs
		1 <sup>st</sup> Interview	2 <sup>nd</sup> interview	Interview with both parents or two family members	
Research Staff (RS)	18	18	6	N/A	0
Community Representatives (CR)	71	37	0	N/A	6
Parents of RVT participants (RP)	20	9	0	2	1*
Parents of MVT participants (MP)	6	4	0	1	0
Community Members (CM)	7	5	0	1	0
<b>Total</b>	<b>122</b>	<b>73</b>	<b>6</b>	<b>4</b>	<b>7</b>
		<b>83</b>			

\*An interview with extended family members

### **Stages of Fieldwork: *Getting in*, *Staying in*, *Pulling Back***

My fieldwork can be divided into 3 stages: *Getting in*; *Staying in*; and *Pulling back*. In referring to these stages in this manner I draw on the writings of Smith (1997); although instead of naming the last stage *Getting out* I call it *Pulling back*. The latter I believe more accurately reflects my relationship as an ethnographer with the field. I do not believe it is possible to get away completely from the field once one has spent a long period there and built up the relationships which are necessary to undertake sensitive and in-depth fieldwork.

The *Getting in* stage covers the period from my arrival in Western Kenya and traces my gradual immersion into the KEMRI/CDC 'trial community'. The *Staying in* stage starts at the



point when I officially commenced data collection and stops at the point when I left the field to return to England. The final stage of 'Pulling back' represents a period of intense analysis and writing up during which I visited Western Kenya on two occasions to verify and discuss interim findings with study participants and colleagues at KEMRI/CDC. To all intents and purpose this stage will continue until the point I feel I have communicated my findings effectively, and have discussed their implications and application sufficiently with academic peers, research collaborators and participants.

### ***'Getting in': February 2007 - September 2008***

My first visit to KEMRI/CDC in Western Kenya was in February 2007 and involved meeting senior Kenyan and American staff at KEMRI/CDC and discussing my research plans with them. Initially these plans focussed on a planned HIV vaccine trial which was due to commence within the HIV research branch at KEMRI/CDC later that year. The HIV research branch is primarily based at a clinical research centre in Kisumu and works mainly with urban and peri-urban communities. The trial was a multi-site vaccine trial which was referred to as PAVE 100. With the permission of trial investigators I was keen to study the implementation of this trial at KEMRI/CDC as a case study in my ethnographic fieldwork.

During my visit the American HIV research branch chief, who was employed by CDC, orientated me to the research set up and infrastructure, introduced me to key personnel and gave me access to relevant PAVE trial documents and protocols. I was able to attend presentations, CAB meetings and a presentation arranged for the visiting deputy American ambassador. I was also given the opportunity to conduct informal discussions with the KEMRI/CDC community liaison officer and staff responsible for community relations in an ongoing HIV incidence cohort study. The former invited me to attend a community meeting during which community members would be nominated to become CAB members for an infant rotavirus vaccine trial (RVT) due to start within a couple of months in a rural area one hour's drive away from Kisumu. This meeting made a marked impression on me and provided me with unique insights into the CE approach adopted at KEMRI/CDC. An appended field notes excerpt describes this community meeting and conveys underlying questions of control in the relationship between researchers and community members and amongst research staff (Appendix I, Doc. 3). International staff responsible for the

coordination of the RVT felt they had to script their input for this meeting and be careful to communicate the pre-decided content without diverting to other subjects. The community liaison officer employed a more relaxed approach in his interactions and this resulted in some strain between him and the RVT coordinators. From the point of view of my thesis this observation is very relevant and speaks to some of the key messages and lesson that arise from my findings.

By the end of my week-long scoping visit it was apparent that the KEMRI/CDC HIV vaccine trial investigators, HIV research branch behavioural scientists and their respective colleagues at the CDC offices in the US were interested in my proposal. A few became research collaborators and provided input and supported the submission of my research proposal to the relevant ethical approval bodies. In Kenya these included (in sequential order) the KEMRI-Centre for Global Health Research scientific steering committee (SSC) based in Kisumu, the Nairobi scientific SSC, and the KEMRI ethics review committee also based in Nairobi. Due to CDC's involvement I also had to apply for ethics approval from the Institutional Review Board based at CDC's main offices in Atlanta. In the UK I had to obtain approval from the London School of Hygiene and Tropical Medicine Ethics Committee. The latter was straightforward and took less than 2 months. The former approval processes were more complicated and took significantly longer than anticipated (May 2007-October 2008). In part this was due to coordinating revisions across two committees which both applied extensive review, and in part it was due to the political violence which occurred following the Kenyan Presidential election in December 2007. A positive consequence of the delay in obtaining ethics approval was that it gave me the opportunity to familiarise myself with my place of study and become immersed in the KEMRI/CDC 'trial community'. I was also able to use this time to start learning both Kiswahili and Dholuo.

During my scoping visit to KEMRI/CDC in February 2007 it became apparent that, apart from my PhD, I could provide technical assistance to the HIV research branch. I have professional training in clinical vaccine research and the HIV research branch director was looking for someone to mentor regulatory staff and the PAVE trial management team during preparations for the PAVE HIV vaccine trial. Hence I moved to Kisumu in June 2007 and was employed as a clinical trials consultant. The remit of my duties was to oversee the protocol

submission to relevant ethics and regulatory authorities, to work with the investigators in preparing the site and to establish a competent team to run the trial. My job description did not cover any of the CE activities for the HIV vaccine trial. These were planned and coordinated by behavioural researchers with the support of community FWs. Hence I was not directly involved in any of the activities which were planned to be the focus of my PhD fieldwork. Furthermore following consultation with the HIV research branch chief we agreed that I would lay aside my consultant duties once I received ethical approval for my research and commenced active fieldwork.

Balancing the role of a clinical trials consultant and PhD student was not without challenges, however combining these roles also provided me with unique insights into the workings of the KEMRI/CDC research programme. Essentially for the period I was employed as a clinical trials consultant, from June 2007 to September 2008, I assumed the role of an 'observing participant'. I assumed certain responsibilities and gained access to areas and situations that would otherwise have been out of bounds for me as PhD student. The way I would balance and perform these two roles was explained to the PAVE trial staff and others, such as the CAB. Valid concerns were voiced by colleagues about my 'positionality' and whether I would be able to maintain objectivity in my PhD research, given my professional involvement in the HIV vaccine trial. We discussed their concerns and I reiterated that I would not continue in the role of a consultant once I commenced my PhD fieldwork. Some of these tensions revealed underlying and understandable resentment about the opportunity I had been given as an international researcher to combine work with PhD studies. Pursuing higher education is highly valued at KEMRI/CDC and I was also earning a good salary as an external technical consultant. These types of reactions are to be expected during the '*getting in*' stage of any project. People were curious and wanted to understand my motives for being at KEMRI/CDC and my reasons for studying a particular phenomenon. In my case there were also some concerns that I might be critical about PAVE related CE activities and that my PhD fieldwork may involve an evaluation of staff members' performance and effectiveness. The main factors which helped to redress these concerns were time, building trust and establishing good relationships with KEMRI/CDC staff and others who formed part of the KEMRI/CDC 'trial community' e.g. CAB members. I also presented my PhD research plans on repeated occasions at KEMRI/CDC seminars to open the floor to questions about my study.

About 4 months into my work as a clinical trials consultant a series of events occurred which led to the initial postponement of the PAVE vaccine trial, and its ultimate abandonment in spring 2008. Interim results from a multi-site HIV vaccine trial being conducted in the US and in South Africa, called STEP, indicated that the trial vaccine being tested in STEP did not prevent HIV and might be associated with increased risk of HIV acquisition in men with pre-existing adenovirus 5 immunity, and in uncircumcised men (Steinbrook, 2007). It was concluded that this was due to the inclusion of an adenovirus vector in the STEP vaccine construct. The PAVE HIV trial vaccine, which was going to be tested in Kisumu and elsewhere, also included an adenovirus vector. Hence after further review of the STEP trial results and high level meetings between PAVE primary investigators and vaccine developers the PAVE trial was abandoned. This course of events resulted in intense discussions at our site during the period when it was not clear whether PAVE would proceed or not. At one point CDC colleagues in Atlanta suggested that we should undertake some community consultation aimed at assessing willingness to participate in the planned PAVE trial. Part of the rationale was to facilitate the inclusion of lay perspectives in decision-making about the continuation or abandonment of the proposed HIV vaccine trial. Whilst this rationale was welcomed by the PAVE trial vaccine team, hesitations were also voiced about the utility of a questionnaire to assess community members' willingness to participate in PAVE. Up until that point community members had not yet been informed about the proposed PAVE vaccine trial. The CAB had been involved in trial preparations but CE activities with the broader community had not yet commenced. Questions were raised about whether questionnaire respondents would be able to comment adequately on the issues at hand, and how this data would be used to inform international high level decision-making. These considerations had implications for the practice of CE in vaccine research, and I applied a critical incident analysis to explore these in detail. The results of my analysis were presented in poster at the AIDS Vaccine Conference in South Africa in October 2008 (Appendix I, Doc. 4). This was one way I used the experiential knowledge gained as an 'observing participant'. The exposure I gained also provided me with a broader perspective of the KEMRI/CDC research programme, and deeper insights into the complexities of applying federal regulations and international ethical guidelines at community level.

The abandonment of the PAVE trial meant that I needed to find new case studies for my PhD fieldwork and amend my research protocol accordingly. I discussed options with my PhD supervisor and senior researchers at KEMRI/CDC. As a result I was given permission to study an ongoing RVT and a planned MVT.

### ***'Staying in': October 2008 - December 2009***

In September 2008 I obtained ethics approval to commence my 'formal' fieldwork. I ceased working as a clinical trials consultant and focussed full time on my ethnographic fieldwork. Hence I changed my vantage point and moved from being an observer participant to becoming a participant observer. The RVT was managed by a team of researchers based in the International Emerging Infections Programme Research Branch and the MVT by a team of researchers based in the Malaria Research Branch. I had not worked for either of these while I was a clinical trials consultant and while the staff knew me they had not associated with me professionally. The fact that they knew me worked to my advantage in that I did not have to explain myself in the same way I had had to during my time in the HIV Research Branch. I was a familiar face and knew the terrain and the people who could help me with the logistics of my fieldwork. This foreknowledge and the quality of my relationships greatly facilitated this stage of 'staying in' and allowed me to undertake my research less conspicuously than if I had only newly arrived at KEMRI/CDC.

The location of my fieldwork also shifted at this stage from the city to the country. The RVT and the MVT both took place in Karemo Division (see chapter 1), a rural area north east of Kisumu. I rented a small office in one of the buildings used by demographic surveillance staff in Siaya, the main town in Karemo Division. I recruited two research assistants to serve as cultural brokers, language teachers, transcribers and translators. These research assistants had had no prior involvement in health research and were resident in the area where the vaccine trials were taking place. One (AS) was a mother in her early 20s who had a professional background in HIV counselling and testing; the other (RO) was a young man who had recently graduated from secondary school and was skilled in computer technology. These research assistants joined me at the beginning of December 2008 when I started

mapping out the terrain in which I conducted fieldwork more closely. To navigate the terrain I hired a car and wherever possible I stayed overnight in Karemo Division. My main residence was in Kisumu where my children were at school, hence I moved back and forth between Kisumu and Karemo during the course of my fieldwork. Some of my fieldwork also took place at the KEMRI/CDC field station in Kisian, which is closer to Kisumu.

In October and November 2008 I focused on observing the final stages of RVT participant recruitment, meeting the CAB and introducing myself to community leaders such as the District Commissioner (DC). My meeting with the DC was important in terms of establishing the premise of my research and my association with KEMRI/CDC. He was interested in my topic of enquiry and thought that it was good that my research was funded separately from KEMRI/CDC. In all my introductions with potential interviewees and other community members I was careful to stress, that whilst I was collaborating with KEMRI/CDC, I was a student from a university in England, and my fieldwork was funded by a charitable trust which supports research. I also reiterated this point on other occasions e.g. when I obtained informed consent from interviewees. However it is possible that community members who were not directly involved in the research - and even some who were interviewed in the study - did not make this distinction. In fact on one occasion I was phoned by the father of a MVT participant several days after I had been to his home with one of my research assistants to interview him and his wife. His daughter was sick and he was asking me for advice on what to do. I stated that he really needed to contact the MVT team and advised him to take her to Siaya District Hospital (SDH) as soon as possible. He said he would and I then alerted the on-call trial clinician to expect them. To a certain extent such mixed understandings about my persona by community members were inevitable by virtue of my colour and position. However I do not believe this detracted significantly from the value of the information which was shared with me by participants. Mixed understandings were not evident amongst community leaders, hospital staff, community intermediaries or research staff.

At the start of December 2009 my research assistants and I conducted a mapping exercise of Karemo Division. Karemo Division is divided into four locations which are administered by governmental chiefs and their assistants. These locations are of relevance to the KEMRI/CDC

research programmes since they form an easy way to organise VRs and CAB members. We arranged to meet the chiefs from these locations at particular times and also invited CAB members from each area to join us at either at the chief's office or a health centre. Each chief provided us with an overview of his area, the geography, the population, and residents' economic activities, the main challenges faced in these communities and the major landmarks. One chief also drove with us around the parameters of his location. CAB members provided us with information relating to their activities for KEMRI/CDC and described community members' perceptions of the research programme. These mapping visits were very useful in orientating us to the individual locations and making contacts with community leaders.

Broadly speaking my fieldwork during the '*staying-in*' stage followed the sequence of CE activities associated with the RVT and the MVT. In Appendix I Doc. 5 I outline all of these CE events chronologically. In the early stages of this period I accompanied the community liaison officer for the vaccine trials (CLVT) on CE events and travelled with her in a KEMRI/CDC vehicle. As I became more familiar with the environment and started to undertake additional research activities such as interviews, I drove with a research assistant to different events. We were made aware of CE activities by the CLVT and were always welcome to attend public forums. On a few occasions the CLVT wanted to meet CAB members on her own; but overall we were given very good access to CE events and also to trials-related activities taking place at SDH and the peripheral health centres. Wherever possible I attended all of the CE activities listed in Appendix I Doc. 5 from October 2009 onwards. When I could not attend I sent one of my research assistants and asked them to compile field notes about the event they observed. I kept field notes of all events and tended to keep these as a form of diary during the course of my fieldwork. In this way I captured more than just particular activities. For some specific CE events and for consent processes we also used observation tools (Appendix I, Doc. 6) which I developed with colleagues from another research institute in Kenya who were also involved in the MVT. We used these tools to collate comparative data about CE in the MVT at two different trial sites in Kenya. Our findings were presented orally at a conference in Liverpool in 2010 (Chantler et al., 2010) (see Appendix I, Doc. 7. for the abstract).

During this stage of fieldwork I interacted with and interviewed senior KEMRI/CDC scientists, community liaison and communication officers, vaccine trial staff (clinicians and FWs), VRs tasked with helping KEMRI/CDC make connections at community level and CAB members who were delegated responsibilities for local representation. At the sites where the trials were taking place I made connections with and interviewed district administrators, a senior leader of the county council, chiefs and assistant chiefs, a church pastor, health professionals and health facility committee members responsible for the clinics and hospitals hosting the vaccine trials, and community members whom I met during vaccine trial-related CE events. I observed events targeted at parents of potential vaccine trial participants and accompanied parents during informed consent processes for the trial. Where possible with the support of my research assistants I conducted follow-up interviews with these parents in their homes.

In terms of data collection my research assistants (RO and AS) were responsible for accompanying me during interviews and observations, interpreting where necessary, and transcribing and translating interviews and FGDs discussions. I conducted all of the interviews with KEMRI/CDC staff by myself since English was the primary language used in these interviews. Interviews held with VRs, CAB members and community leaders such as the DC and chiefs were also primarily held in English although interviewees occasionally used Dholuo or Kiswahili to illustrate certain points. Interviews with parents of RVT and MVT participants and some community members were conducted in Dholuo. I attended most of these interviews and either RO or AS would interpret for me, otherwise the interview would be conducted in Dholuo by RO or AS and translated following transcription. My aural understanding of Dholuo increased significantly during the course of my fieldwork and I could follow the content of interviews in Dholuo but found it more difficult to communicate in spoken Dholuo. I could initiate conversations and cover certain subject areas but was not able to facilitate an interview or focus group discussion in Dholuo. Working with a team of local research assistants helped me significantly in this regard and also allowed me to learn more about the local culture and environment.

As is customary in ethnographic research I undertook some initial analysis of the data while I was still involved in fieldwork. This helped me to revisit issues that came up during observations and interviews and to explore emerging questions. One topic area which



repeatedly arose was paternal hesitancy and occasional resistance to the participation of children in vaccine trials. In order to explore this topic area in more depth I recruited an additional research assistant. This research assistant (PO) was originally trained as a nurse and had experience of working in health research and was currently enrolled in Masters level study in community health and development at Maseno University near Kisumu. He originated from Nyanza, was of Luo ethnicity and was married with one child. The latter was of particular relevance to the sub-study we developed for him to undertake for the requirements of his Masters studies. The main aim of this study was explore fathers' understanding and experience of health research and their views concerning the participation of children in vaccine research.

My fieldwork drew to a close in December 2009 and before I left Kenya I presented some initial findings for discussion with research staff at KEMRI/CDC. This was a useful exercise and led to constructive exchanges and a draft manuscript which I wrote with some input from collaborators from KEMRI/CDC during the '*Pulling back*' stage of my fieldwork.

### ***'Pulling back': January 2010 - ongoing***

I refer to this stage as '*Pulling back*' rather than '*getting out*' as it has involved leaving and returning; returning both physically for short field visits and intellectually through immersion in my data. I have been based in my home town, Oxford, during this stage and have had access to the Oxford University libraries. These have provided a space to think, read and consider my material and related literature. At first I concentrated on sorting, checking and organising my data and then I proceeded with an in-depth analysis. Alongside this analysis I started to think about the organisation of my thesis and how to present my data. I started writing the findings chapters and worked on a few abstracts and a manuscript. Writing the findings chapters was an intense and lengthy process and it became evident that I had a wealth of information to convey. The breadth of my data provides a wide angle lens on the practice of CE and omitting any would have detracted from the full picture I was seeking to capture.

In June and September 2010 and in April 2011 I returned to KEMRI/CDC for short trips of between 1-3 weeks. During these visits I worked with PO on the Fathers Study data, visited the places where I had conducted my fieldwork and verified and discussed some of my interim findings during presentations with KEMRI/CDC staff, CAB members and a few SDH staff members. I also participated in workshops with wider audiences. Such activities and ongoing communication with manuscript co-authors from KEMRI/CDC enabled me to hone my writing and present a valid critique which portrays the challenges encountered in CE transparently and constructively.

It has been very important for me to find a space away from my field of enquiry to reflect carefully on my work and findings. I needed to draw away from the immediacy and the politics of the field and reflect on my experiences from a critical distance. This helped me to distil my arguments and theory and express these in a measured and authentic manner. My subject area is sensitive and my findings have implications for the KEMRI/CDC research programme; hence I have chosen to involve key people at KEMRI/CDC in some of my publications. This has been a valuable exercise as it has given us the opportunity to think through complex issues which are affecting practice and to consider together ways of addressing these. It is also a challenging process and has required me to state my case clearly and ensure that my arguments are cogent, constructive and measured. The writing of this thesis has been both instrumental in this and partly shaped by this, and it will form the basis of future publications.

## **Data Analysis**

The scope and nature of my research questions and study objectives meant that I could be flexible and iterative in my fieldwork. One of the key advantages of adopting an ethnographic approach and committing a period of 2 years to my fieldwork was that it allowed my interviews and informal conversations to be grounded within the realities I observed. I was able to follow up on observed events in interviews and discussions which allowed me to explore different peoples' perspectives of these. This triangulation of what I

saw for myself with what people said is evident in the presentation of my findings where I use descriptions of social situations to add depth to interview data.

My primary collected data comprised of observational field notes, interview transcripts, study participants' demographic information and source documents including KEMRI/CDC publications and standard operating procedures. The interviews and FGDs were recorded digitally and subsequently downloaded to a computer programme and transcribed (and where necessary translated) into Word files. I checked all the interview transcriptions for accuracy by listening to the digital recordings and cross-checking them with the transcripts. I highlighted areas which needed additional attention or were not audible and asked my research assistants to look at these again. Transcripts were stored on password-protected computers and participants' demographic information, data backups, paper copies of the transcripts and field notes were kept in locked cabinets when they are not being used. Access to these materials was limited to the research team.

Data collection and analysis occur concurrently or in alternating sequences in qualitative research which allows interim findings to inform the ongoing research process. The analysis which took place during my fieldwork was iterative and involved me talking about the data with my research assistants and collaborators, recording reflections in my field notes and discussing particular issues with my supervisors. Particular issues or questions which arose during interviews or observations informed my subsequent fieldwork. For example I began to look much more closely at CE with health facilities as the result of a FGD with hospital staff.

I started a more systematic analysis of the data towards the end of the 'staying in' stage of my research. By this point most of my interviews had been transcribed, checked and corrected so I was able to import them into a qualitative data software programme (NVivo). I also imported my field notes which I had copied electronically and source documents e.g. CAB members' reports and standard operating procedures relating to CE. Storing my data in one place allowed me to organise them and commence a systematic analysis. I used a thematic approach for analysing my interview data (Green and Thorogood, 2004 p.177). This approach involves the following steps: familiarising oneself with the data; initial coding, developing a coding framework; applying this framework to the rest of the data; looking for

cross-cutting themes; and revising the framework where necessary. I also took care to embed my findings in the contextual data contained in field notes and other source documents. My overall aim was to generate an explanatory and descriptive analysis which would allow me to draw meaningful and accurate theoretical and practical conclusions.

## **Conclusion**

This chapter has presented a detailed account of my fieldwork and an overview of the methodology, data collection methods and the approach to analysis I applied in writing up this thesis. While appropriate given my ethnographic study methodology, in part I also chose to provide a very detailed portrayal of my fieldwork in order to allow readers to judge and consider critically for themselves how my presence and position may have influenced and facilitated my research.

## Chapter 4:

# The History of Community Relations at KEMRI/CDC

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*'Right from the beginning, the community engagement was there. I think it's stepped up but I don't think there was ever a time that you know, like a study was done and n- one, because you know could not imagine, you could never really do that, you have got to talk to somebody [yeah]. So you talk to the chiefs and you have a community meeting, then you might meet with the DHMT (District Health Management Team) at the hospital... '*

*Senior American Scientist, RS 14*

## Introduction

In this chapter I trace the history of community relations at KEMRI/CDC. To construct the story of community relations at KEMRI/CDC I reviewed published papers from the 1980s to date which contained some description of how trials were implemented at district and community level, and corresponded with three of the authors by email, and held a telephone interview with one of these. In addition I drew on my field notes and talked in person and by email to six researchers who had been attached to KEMRI/CDC for 5 years or longer. These discussions provided important insights and illustrated the risk of projecting contemporary concepts such as 'community engagement' onto past practices; hence in this chapter I apply the broader term 'community relations' in order to capture the full range of interactions between researchers and the community.

In chapter 3 I argued that the genesis of the concept 'community engagement' in international health research can be traced back only to the mid to late 1990s. KEMRI/CDC was founded in 1979; hence it can be problematic to apply the term CE to past interactions between KEMRI/CDC researchers and the community even if some of those activities are also associated with current practice. In the above-cited quotation a senior American scientist focuses on the initial stages in community relations, which require researchers to

follow inherent and established social and cultural etiquette and official protocol. These community entry stages are arguably fundamental prerequisites. However they do not encompass all aspects of community relations and are not equivalent to CE. In this historical narrative I will present other facets of community relations and identify precursors to the way in which CE is currently framed at KEMRI/CDC.

## **Historical Narrative of Community Relations at KEMRI/CDC**

In the immediate area where I carried out ethnographic field work, trials on health interventions that will be applied on a community-wide basis (community-based trials) are relatively new phenomena. Most of the research conducted in Karemo Division during the 1980s and 1990s took place within the paediatric and maternity wards and the outpatients clinics at Siaya District Hospital (SDH). These observational studies evaluated paediatric and maternal mortality related to malaria, anaemia and HIV, assessed blood transfusion practices and validated an algorithm for integrated management of childhood illnesses (Lackritz et al., 1997, Perkins et al., 1997, Zucker et al., 1994). The validation of the algorithm included a comparison of the performance of a minimally trained health worker and a trained paediatrician, who, in contrast to the health worker, had access to laboratory and radiological support. In terms of contact with study participants' home and community environment Lackritz (1997) acknowledges '*J. Ochieng for effectively conducting the follow-up in unmapped, unmarked, remote areas*' but makes no further reference to this aspect of his longitudinal evaluation of severe anaemia in children. To conduct these studies researchers collaborated most closely with their official counterparts from the Ministry of Health which included members of the District Health and Management Team (DHMT), the hospital medical superintendent, the district medical officer and the hospital staff. This official collaboration is one of the fundamental prerequisites which have been particularly prominent throughout the history of KEMRI/CDC. To explore other facets of community relations I will draw on experiences from community-based trials and related projects that took place in the rural areas of Asembo and Gem which lie adjacent to Karemo (see Map 2).

## ***Saradidi Community Health and Development Programme***

The Saradidi community health and development programme was initiated by a church congregation in 1979 (Kaseje and Sempebwa, 1989). Its origin was a development education programme run by the Anglican diocese of Maseno South. This course provided participants with the impetus to become involved in health and development activities. They mobilised the community and accessed funds from the Anglican church to set up a health and development programme. To strengthen this programme community leaders invited outside health and development professionals to assist them in the process of defining their problems and identifying ways to solve them as a community. Kaseje and Sempebwa (1989) stress that *'the role of outsiders was to facilitate the process'*. They describe how the community developed its own support structure and health programme by drawing on internal and external resources. The support structure comprised a management board, whose members included teachers, village elders, chiefs and church members, and village health committees who were responsible for health activities taking place in their respective villages. The emphasis on community participation in the Saradidi programme reflected core ideals conveyed in the WHO Alma Ata Declaration on Primary Health Care (World Health Organisation, 1978).

*'Primary Health Care... requires and promotes maximum community and individual self-reliance and participation in the planning, organization, operation and control of primary health care, making fullest use of local, national and other available resources; and to this end develops through appropriate education the ability of communities to participate...'*

In the Alma Ata Declaration primary health care (PHC) was presented as a matter of social justice, which would enable all people to achieve a good level of health and live socially and economically productive lives. It was viewed as an integral part of health-care systems which merited increased levels of funding and technical support. Much emphasis was placed on responding to the expressed healthcare needs of communities and strengthening pre-existing health-care solutions, such as traditional birth attendants.

One of the health priorities identified by community members in Saradidi was for people to be trained in matters of health in order to teach and assist others and to serve as 'agents of

change'. In response a village health helper curriculum was devised based on the problems and needs of the community, and a trainer was provided by the Department of Community Health of the University of Nairobi. This link was facilitated by Dr. Kaseje who originated from Saradidi and who was working as an epidemiology lecturer within that Department. Dr. Kaseje also collaborated closely with other health institutes including researchers attached to KEMRI/CDC. A professional relationship between him and an American physician was of particular note both for the development of the Saradidi programme and the future work of KEMRI/CDC in Nyanza province.

In the early 1980s Dr. Spencer, a physician in his late twenties, moved to Kenya to work with KEMRI/CDC. Motivated by personal interest he visited the Department of Community Health in order to learn more about their teaching programme and research. This visit resulted in Dr. Spencer being offered an honorary appointment by the University of Nairobi. He shared a lectureship with Dr. Kaseje which allowed them both to pursue research interests within the Saradidi programme. Their role in this programme was to provide technical support for a malaria control project. As part of this work Dr. Spencer and Dr. Kaseje identified research gaps which they discussed with the Saradidi programme's management board. Because the management board were keen to know whether their activities had resulted in improvements to health, for example a decrease in infant mortality, they were convinced of the need for research.

With the support of the management board and KEMRI/CDC Dr. Spencer and Dr. Kaseje built up a research team. This included laboratory technicians, entomologists, statisticians and social scientists. Research activities were supported by WHO and mainly aimed at evaluating the effectiveness and impact of malaria control strategies, and assessing the sensitivity of malaria to different drug regimes. Individual research projects had to be approved by the management board and the purpose of research activities was also discussed in community forums and meetings with parents where studies involved school children (Spencer et al., 1983). Researchers were accountable to the Saradidi management board and the board reserved the right to stop any research study if concerns arose. This occurred in a trial trying to establish the relationship between salt intake and hypertension. Board members were not convinced of the relevance of this trial for local health priorities,



and community members expressed anxiety about trial procedures which included taking a salt tablet.

The main purpose of research activities at this time was to strengthen and improve services provided by the Saradidi health and development programme. This programme was significantly shaped by the Alma Ata philosophy of community participation. The influence of this philosophy and 'bottom-up' approaches to development can also be traced in the following excerpt from Dr. Spencer's curriculum vitae (Spencer, 2011).

*'..the main focus of my time in Kenya was in the Saradidi Rural Health Development Program, a research, teaching and service program based at Saradidi a community of about 50000 people in western Kenya, on the shores of Lake Victoria near Kisumu. Mentored by Dr. Dan Kaseje, the Kenyan senior project leader, I worked with him to train a network of community health volunteers that would provide medical and preventive services directly to the people living in their village .... We worked in full partnership with the people of Saradidi who maintained control of the program throughout'.*

Dr. Spencer's references to his 'mentorship by a Kenyan senior project leader' and the way the project 'worked in full partnership with local people, who maintained control of the program' are significant. To a certain extent they justify his position; but more critically they shed light on underpinning aspirations about the nature and function of collaboration at that point in time. It is also important to remember that research activities and related protocols did not drive the agenda but played a supportive role in achieving the overall goal of improved health for local residents. Indeed the success of this locally-initiated health and development programme has been attributed to community members maintaining responsibility for the direction of the programme (Kaseje and Sempebwa, 1989).

The material presented in this section is based on my review of relevant literature and related documents. More importantly, it is informed by an interview that I conducted with Dr. Kaseje about the development of the programme and subsequent integration of research activities. Whilst these sources provided me with valuable insights I cannot be sure whether recollections contained in documents or shared with me verbally adequately reflect the reality at the time. Despite this limitation it is evident that community-driven

healthcare, and to a certain extent community-controlled research were conceived of being the ideal at this point in time.

### ***Expansion of the KEMRI/CDC Research Programme***

The growth of externally-funded research on the epidemiology, entomology, and immunology of malaria during the 1990s (Bloland et al., 1999, Phillips-Howard et al., 2003, Ter Kuile et al., 2003) precipitated a gradual shift in the locus of control in the conduct of KEMRI/CDC studies. KEMRI/CDC developed extensive research infrastructures in Western Kenya including central office and laboratory facilities on the outskirts of Kisumu. The impetus for studies no longer arose from direct interaction with community-based health programmes but reflected an 'internationally defined' research agenda. National and expatriate researchers aspiring to contribute to scientific progress became increasingly accountable to external sponsors and host communities no longer played a dominant role in overseeing research activities. More broadly, community-led health and development initiatives were no longer seen as the ideal or the norm.

Local involvement in research was mainly limited to the recruitment of traditional birth attendants (nyamreche) and other community health workers to assist with a wide range of clinical tasks on a casual basis. These tasks included obtaining blood samples and smears, performing malaria tests, measuring temperatures and administering oral anti-malaria medication. The trend of delegating specific research tasks to community health workers is exemplified in a large community-based randomised control trial of insecticide-treated bed nets that took place from 1996-1999. This trial covered a vast area of 500km<sup>2</sup> which included 79 villages in Asembo and 142 in Gem and encompassed a total population of 125,000 (Phillips-Howard et al., 2003). Over 300 nyamreche were enlisted as casual employees to be a grassroots link between project staff and village residents. Some of them were promoted to more senior positions within an established network of local supervisors. Nyamreche were involved in educational activities such as composing songs and were trained to obtain household consent, complete basic demographic questionnaires and dip the intervention nets at regular intervals. They were paid daily or half-daily rates of Ksh 100

(approx US \$ 1.30 at the time) or 50 respectively; the Ksh 50 rate was generally reserved for composing educational songs, attending barazas (open community meetings facilitated by administrative chiefs) or weekly nyamreche meetings. In my email correspondence with Phillips-Howard (2010) she elaborates further on employment-related benefits and captures KEMRI/CDC's main motivation for working with local nyamreche at that point in time.

*'...We also supplied them with their own gumboots, umbrellas for rainy season. Quite a few also had bicycles if they had some distance to travel. Interestingly at one point they requested a uniform, but after long discussions between them and the office in the end this did not happen – I think they felt they wanted to stand out as different from community, but our take on it was that it was because they were part of the community that they did so well in their work, and were trusted by the community'.*

The nature of the involvement of village members in health and research tasks is of interest in this 1990s narrative of community relations. Informed by the ideals of community participation village health helpers had been viewed as 'agents of change' in the 1980s Saradidi self-help health programme. But as the KEMRI/CDC research programme expanded increasing attention was paid to their role in facilitating research as those who were 'trusted' by other community members. The nature of tasks delegated to them also changed as a growing body of contracted field workers took over more technical responsibilities. In essence we see younger, more qualified community members becoming part of the KEMRI/CDC workforce whereas most of the community health workers and nyamreche continued to be affiliated to research studies on a casual basis. Of note here are inherent distinctions in status between nyamreche and field workers. Nyamreche are usually older women whose age, experience and child-bearing afford them much respect at community level. Field workers in contrast are secondary school leavers who gain employment by virtue of their academic qualifications rather than their positions within the local community.

### ***Community Relations made Visible in the Biomedical Literature***

An article which describes the development of the infrastructure for the insecticide-treated bed net (ITN) trial contains several sections about community mobilization and educational activities. The way in which community processes are made visible by Philips-Howard et al (2003) is significant since reports on biomedical research do not usually include much detail

relating to these aspects of research preparations. Partly the rationale can be understood given the high profile of this trial in terms of the national malaria control agenda and the fact that it involved whole communities rather than individuals. It is also of interest, that whilst Phillips-Howard et al (2003) do not refer to ethical requirements their article coincides with the emergence of the concept of CE in literature about the ethics of international health research.

Phillips-Howard et al. (2003) relate how community mobilisation commenced with meetings with government officials (district officers, chiefs, and assistant chiefs) to explain the purpose of the bed net study. Subsequently, barazas were conducted in each of the 33 sub-locations in Asembo and Gem to allow villagers to ask questions about the proposed trial. These meetings were attended by several hundred adults who were thought to represent a substantial proportion of adult villagers. Local language and English leaflets describing the project were distributed and researchers responded to questions about net ownership and use, the possibility of employment with the project, and details of malaria transmission, prevention, and treatment. These meetings are described as being a way of obtaining authorization from those present for the trial to be conducted in their sub-locations.

Having obtained community approval, the authors describe how voluntary village ITN trial committees were established to assist with communicating information about the trial. A volunteer from each village was also elected to represent their village at the randomisation lottery. At this public lottery the village representatives chose a sealed envelope from a basket containing hand-written tickets. Each ticket determined whether a village received the trial intervention or not. This public lottery was witnessed by national and local officials, who had been invited to the public launch of the bed net trial. At this stage community mobilisation had a primarily educational focus. School children participated in drawing and poetry competitions, nyamreche wrote songs about the study and local actors were trained in participatory educational theatre (PET). Songs and skits were performed at public meetings, schools and traditional functions and PET actors visited all of the villages at least once prior to net distribution. The following quote from Philips-Howard (2010) provides insights into the relationships between researchers and nyamreche and stresses the

iterative nature of these educational elements, which at that stage did not require formal ethical review.

*'Interesting question about ethics for the songs – no, they did not each go back to ethics as it was an iterative and unique process – each sector office group developed songs and we even had a competition where the nyamrerwa (nymareche) from the sector office were awarded a prize for their winning song (a kanga each I believe). They often make songs which were sung-independently of our involvement-at local barazas, so the ones they created for the project were considered more a strengthening of their traditional role in the community than a 'research' component. A couple of the songs we heard as early versions had to be amended because they were more like 'odes to CDC'... we love you Dr (X) you are so strong; Dr (P) is so beautiful (ha)... After discussing with them the rationale for the songs was to help provide understanding to the community about malaria and care of sick children (e.g. go to clinic early if child sick), and looking after the bed net properly, they 'upgraded' their songs!'*

The published account (Phillips-Howard et al., 2003) of the development of the ITN trial site refers to fundamental prerequisites in community relations i.e. the approval by official leaders. However it also describes how researchers sought to foster a much broader community involvement by the use of participatory techniques. The nature and size of the trial and the fact that it was not part of an existing health project meant that researchers had to pay closer attention to how to galvanise public support. Another point of interest to this historical trajectory is that locally-developed and sometimes impromptu educational components did not require the same level of ethical review which is currently mandated by institutional review boards at CDC.

### ***Development of a Health and Demographic Surveillance System***

Building on the infrastructure created by the ITN bed net trial, KEMRI/CDC started to develop a health and demographic surveillance system (HDSS) in 2001. The aim was to transition from holding a periodic census to continuous demographic surveillance using tools developed by other surveillance sites in developing countries. To achieve this goal a Ghanaian researcher, Dr. Adazu, who had worked at one of the first surveillance units in Africa (Navronogo HDSS, Ghana) was initially hired as a consultant and later appointed as the Chief of the KEMRI/CDC HDSS. The Navronogo HDSS had been a founding member of

INDEPTH (*The International Network for the Demographic Evaluation of Populations and Their Health in Developing Countries*), a strategic international network of field sites conducting demographic surveillance in developing countries. Dr. Adazu's experience facilitated KEMRI/CDC's entrance into INDEPTH and helped to strengthen KEMRI/CDC's position as one of the leading players in the arena of international collaborative health research.

The appointment of an African scientist to this senior position of leadership was viewed very positively by KEMRI/CDC staff and national and international collaborators, and Dr. Adazu's work ethic and strong leadership gained him a lot of respect. He developed clearly defined operating procedures and demanded very high standards from his team; any field staff members caught falsifying data were fired without recourse. Interestingly the broader community generally accepted this zero tolerance approach, and after his unexpected death in January 2009 a district health stakeholders' meeting was interrupted to hold a minute's silence in his memory.

The idea of the HDSS was first presented to community leaders and local residents in Asembo and Gem during the dissemination of results from the bed net trial. This was followed by ongoing community-based discussions to explain the purpose of the HDSS and its implications for participating households. In terms of implementation the next step in developing the HDSS was to use a satellite-enabled global positioning system to map all of the houses, villages and towns within the specified surveillance area. Initially this included only the areas where the bed net trial took place, Asembo and Gem. Subsequently the HDSS area was extended to incorporate Karemo division in 2007. After the mapping exercise field workers visited the household heads to explain the purpose of the HDSS and obtain their consent to be included in the surveillance system. Households who agreed to become part of the HDSS were given a unique location code which was painted on each house (see photo 5). These codes consist of symbols and numbers to identify the village, compound and the house (V stands for village).



**Photo Number 5:**

**HDSS Household Location Code Marked on the Door of a House**

(Acknowledgement: G. Jones)

Individual residents in turn were allocated a permanent identification number composed of this location code plus a three-digit individual number. Households who withheld consent were not included in the surveillance system although they still appear in annual updates of satellite maps. Earlier in this chapter I cited Lackritz's (1997) acknowledgment of '*J. Ochieng's contribution to effectively conducting the follow-up (in a longitudinal evaluation of severe anaemic children) in unmapped, unmarked, remote areas*'. The advanced mapping process outlined above contrasts with Lackritz's description of follow-up. In the HDSS uncharted territories became mapped and were recorded with advanced technology.

Today the KEMRI/CDC HDSS includes a total of 385 villages across Asembo, Gem and Karemo; in Karemo alone this amounts to 19,000 households. Surveillance is conducted every four months through house-to-house interviews conducted by local field workers who are trained to collect demographic, health and socio-economic data. The information thus

obtained is supplemented by regular reporting of births and deaths by VRs. A VR is an individual selected by the community members to support the implementation of KEMRI/CDC projects and studies. I will expand on VRs role and conditions in chapter 7.

At KEMRI/CDC the HDSS is viewed as the backbone of the research programme and presented as a key asset in reports and funding applications. Conducting trials within demographic surveillance areas can augment the scientific credibility of findings and is viewed favourably by regulators. Maintaining a HDSS requires long term commitment and significant investment, which can be difficult to attract since sponsors are more interested in funding health interventions. The main purposes of the HDSS are to facilitate the evaluation of future population-based public health interventions, generate hypotheses and help address the causes of morbidity and mortality (Adazu et al., 2005). Whilst these outputs are very important from a research perspective they provide no immediate benefit for households who are requested to provide sensitive information about family members' health and socio-economic conditions on a regular basis. A chief from Karemo recalls how community members initially responded to the idea of a HDSS in the following interview excerpt.

*'...the part of properties is what brought contentions because those people asked, why do you want to know my radio, why do you want to know my animal, do you want to steal my animals? People asked a lot of questions there, but they were told that one was purposely for the recording and knowing whether you are improving in lifestyle or not. So they were also convinced and from there we rolled it down to the sub-locations mobilizations and then from there they (KEMRI/CDC) told as they were going to employ some of our children to do the work of interviewing they will not get people from outside because they (the community) don't want people from outside to know their secrets [laughter].*

*Chief and CAB Member, CR 05*

Community members were suspicious about researchers' intentions-for example police living in urban quarters associated health surveillance activities with spying. Many people were reluctant to disclose information about their assets and economic status and some wondered what they would receive in return. A CAB member from Karemo noted in a monthly report dated May 30<sup>th</sup> 2008, that *'villagers are worried about why the CDC keeps on asking what they possess at the moment, after which no contribution is made'*. This



perceived lack of exchange led some to complain to VRs that *'you are gaining from our name but we are left poor'* (VRs, CR 28). The 'you' in such remarks relates to anyone involved in the research programme. Repeated home visits and unrelenting questioning led to fatigue and resulted in *'villagers hiding from the field worker, they were fed up with all the questions they were asking, and yet people are hungry.'* (CAB member report, dated 8<sup>th</sup> April 2008). According to a male development worker in his twenties more feedback on the rationale for demographic health surveillance was required. To press this home he posed the following rhetorical question during an interview with one of my research assistants.

*'...imagine a situation Mr. Peter [mmm], where somebody comes and interviews you at your home there, you have how many cows, and he goes like that, without telling you his or her intention with your cows. You will question, you get, you will remain with some questions, as he goes [yeah], you remain with some questions [yeah, yeah].'*

*Community Member, CM 03*

Such responses focused attention on the need to address community concerns in a more formal manner. Significant material and financial investments had been allocated to setting up the HDSS and researchers realised that they could not afford to jeopardise its success by neglecting such matters.

### **Formalising Community Liaison Activities**

The development of the HDSS in 2001 and an associated increase in community-based studies seeking to address public health questions in the fields of malaria, HIV and schistosomiasis precipitated the need to formalise and prioritise community relations. An existing Luo-speaking Kenyan employee, with a degree in Zoology, was appointed to the position of Community Studies Head. The Community Studies Head had an office at the main research facility in Kisian but spent most of his time in the field. His primary role was to ensure the continued support of community and political leaders and make certain that the public were informed about on-going projects and their results. He was also responsible for supporting the implementation of studies, supervising those in charge of information, education and communication activities and managing VRs. As part of his job he established the first KEMRI/CDC CAB in 2003 to assist with preparations for a baseline cross-sectional

survey of sexually-transmitted infections among individuals aged 13-34 living in the Asembo area (Amornkul et al., 2009). CAB members were asked to provide researchers with specific feedback about the wording and cultural acceptability of a sexual risk behaviour questionnaire, to relay community concerns and to comment on questions of assent and consent. Following this pattern CABs at KEMRI/CDC tended initially to be set up to serve specific studies. But as they became more established they later broadened out to include other studies. The broader model has some advantages in terms of synergising efforts and maximising information. However it can also limit the level of input CAB members can contribute to individual studies. The modalities involved in setting up a CAB, selecting CAB members, defining their roles, remit and accountability will be described in more detail in chapters 5 & 8.

At the start of 2004 researchers conducting biomedical trials in the Asembo area became the subject of negative press reports, which claimed that they were tricking community members into joining studies and using them as 'guinea pigs'. This type of reporting on research is a common phenomenon in East Africa and reoccurs on a regular basis. The main article in question in this instance was published by the East African Standard (Big Issue Team, 2004) (Appendix II, Doc. 1). The journalists were critical of the government's failure to investigate claims that Walter Reed, a research unit of the United States Army, was subjecting community members to unethical research procedures. Their article included photographs of research participants, who asserted that they had been lured into research by the promise of free food and financial benefits without being told about the real implications of the research. According to a project officer who was working with Walter Reed at the time there were no records of the main complainant ever having taken part in the study cited in the article. Routine reports conducted by external study monitors also did not substantiate the article's claims. After further investigation by Walter Reed it was determined that those cited in the article were influenced by a disgruntled former employee whose contract had not been extended. This conclusion has become the widely accepted narrative used by researchers to explain this incident.

Of note in terms of this episode in the historical narrative is that local residents do not always differentiate between research groups. Furthermore both CDC and Walter Reed are

American research units that work in collaboration with KEMRI. Hence, while KEMRI/CDC was not directly implicated in these events the incident drew attention to the need to rethink the way in which community relations were organised across the research programme.

By the middle of 2004 the Community Studies Head left this position to coordinate a large malaria drug trial in Asembo. Therefore KEMRI/CDC advertised for a new community liaison officer (CLO) to be primarily responsible for coordinating community relationships in all of the study areas. The idea was to narrow the remit of this type of position so that the officer would not have any direct responsibilities for studies. The CLO's main duties were to strengthen community relations, oversee the work of VRs, be a point person for CABs and to support study coordinators in their interactions with local communities. A male Kenyan of Luo origin with a background in secondary school education in Kenya and the UK was appointed as CLO in 2005. Shortly after he took up this position the American leadership at KEMRI/CDC changed. The previous senior scientist, who is a clinician with expertise in malaria, returned to CDC's main offices in Atlanta, and a female epidemiologist with a science doctorate took over in September 2005. The scope of the KEMRI/CDC research programme had grown substantially in the five years prior to her appointment. Previously malaria research and demographic surveillance had been the main foci of activities at KEMRI/CDC; however the portfolio had expanded to include HIV research in 2001, international emerging infectious diseases (IEIP) in 2004, and Tuberculosis in 2004. When the new senior CDC scientist arrived the KEMRI/CDC programme was organised into 5 research branches: Malaria, HDSS, HIV, IEIP and Tuberculosis. Each branch had a scientific lead and therefore, unlike previous CDC leaders, she did not have to balance leadership and management responsibilities with providing detailed oversight of individual studies. According to an American investigator this allowed her *'to take a global look at the program and address deficiencies'* (RS, 13). Of pressing priority in this respect was the need to support the work of the CLO, and to identify ways of responding to increasing demands for accountability at community and district levels.

*'Um, so Matthew (CLO) was actually hired right before I came and he was hired because there were issues and everybody felt they needed a centralized community person so I don't know all the pieces before I came, but certainly the like heavy dutiness of it, and like Matthew's constant meeting with everyone has and was only really started when I got here and has only increased year by year like where we learn, oh we need to include the city council chairman and so now we need that meeting, and we need to include the teachers and we need to include these opinion leaders and those people we have to do a courtesy call to the DC (District Commissioner), all that has been like in the last couple of years of learning who feels like we are not totally including them. I think that generally the relations are much improved like Linus (previous CDC director) said to me that he thought you know, because he was here before that, that relationships in the community were very much improved and also it's been an education process for the community of who KEMRI/CDC is and all the research. I mean ten years ago things were brand new in some communities so a lot of it has just been getting used to KEMRI/CDC, not necessarily any of the efforts we have made.'*

*Senior American Scientist, RS 14*

This excerpt from an interview with the CDC director suggests that encounters between researchers and the lay public are now characterised by mutual learning and familiarisation; researchers become skilled at negotiating obligations and community members are exposed to and get used to the technicalities and benefits of research. It also makes several explicit statements about the direction of inclusion and agent of inclusion. In this excerpt the CDC director repeatedly says that 'we' need to do such-and-such in order for different groups to feel included. This suggests that KEMRI/CDC has become the agent of inclusion and that community liaison activities are directed from the research institute to the community. However as I will expand on in chapter 9 community leaders - 'gatekeepers' - have also started to demand more accountability from KEMRI/CDC and other research institutes and non-governmental organisations working in Siaya District.

In continuing conversations it was very apparent that the CDC leadership places much confidence in information dissemination as a means of smoothing the path of research and overcoming hostility. This was the rationale for developing a communications team under the leadership of a female Kenyan graduate communications specialist who was appointed in October 2007. Over the past three years this team has produced a wide range of publications (see chapter 5 for more detail) and worked with field staff and scientists to help them communicate more effectively with local and national stakeholders, including the

media. The following quotation aptly illustrates the drive to produce written materials which can reach everyone.

*'.....we have the brochures we have that community newsletter, we haven't had very many issues yet but um the idea of that is that you know, half in Luo and half in English, I mean it is both in Luo and in English. To really give and like just flood the community because the thing that most worries me is that you somehow you reach this set of people and you never reach this set of people whether it is the men, whether it is just the people who are working, and then you find from them that they think that they have never been reached, and that we have never reached them and so they give this impression that somehow we are not communicating, you know, so there is a disconnect because we don't somehow reach everybody. We reach probably some people all the time [yeah] and then probably another group of people never and so if we do more of the written materials it seems to me that if you just have it in every household, somehow you are communicating, you know, more.'*

*Senior American Scientist, RS 14*

The underlying questions about communication, inclusion and disconnection articulated in these interview excerpts have a significant bearing on KEMRI/CDC's current approach to CE. They also resonate with a recurrent theme in this chapter, namely the influence of *'the exercise and experience of control in the conduct of research'* on the practice of community relations.

### **Growing Presence and Visibility of KEMRI/CDC**

The growth in research activities, in particular community-based studies, the development of the HDSS and the increased employment of local residents have all resulted in KEMRI/CDC becoming more visible at community level. The majority of employees are Kenyan and many originate from the areas where research is taking place. In fact in order to qualify for some positions applicants have to be local residents. This is the case for FWs who support the day to day running of trials. These positions are very sought after at community level and the application process is very competitive. Applicants need to have completed secondary school and achieved at least a C grade in their final examinations. Positions are advertised on notice boards at chief's offices, clinics and hospitals. These notice boards were erected by KEMRI/CDC in response to requests for more transparency about

employment practices and opportunities. The notice boards are used to advertise a range of employment positions not just those available at KEMRI/CDC.



**Photos 6 & 7: Notice Boards at Chief's Camps in Siaya District**  
(Acknowledgement: G. Jones)

Employment opportunities are scarce in the rural communities where KEMRI/CDC works. Hence many people and in particular school leavers aspire to work with KEMRI/CDC. In fact job applications, short-listing and interviews represent another form of CE; one which is characterised by aspiration, imaginations of opportunities and in many cases disappointment.

FWs are employed on annually renewable contracts and undertake a range of duties. These include home follow-up of participants, data and sample collection, recruitment and consent activities and any other work delegated to them by fieldwork supervisors and study coordinators. To complete their duties FWs move from place to place by motorbike or bicycle making them very visible. They also mix socially with their local community which serves to increase awareness of KEMRI/CDC. A case in point is a traditional healer, who first learnt about KEMRI/CDC when a fieldworker came to him for help in a personal matter unrelated to physical health.

While there is no official career structure for FWs some have benefited from further internal training and gone on to become study coordinators and investigators in their own right. Whilst it is a general policy to employ local residents as FWs they usually do not operate in their immediate home areas. Questions of confidentiality have led to FWs being stationed in adjacent areas where they are less well known. From a community perspective it is very important that young people from local areas are not disadvantaged in terms of employment possibilities. Community members voice a strong preference for FWs to identify themselves as coming from the area, to be native Dholuo speakers and to understand the local environment and cultural context.

The way in which KEMRI/CDC has become part of the fabric of the community has fostered community relations in a positive manner, although as noted earlier in this chapter discontent amongst local staff can have negative repercussions. Overall however a strong local presence does seem to have served to familiarise people with the idea of research; a notion which I will explore further in subsequent chapters.

## **Discussion of the Main Themes**

Two core themes arising from this chapter are the experience and exercise of control in the conduct of research, and the 'direction' of interactions between researchers and communities. Who is responsible for community relations, who initiates relations, who includes whom and why, who manages ensuing communications and what is the nature of this conversation, is it one or bi-directional?

Looking historically we first encounter control in the social and cultural etiquette and official protocol international and national researchers have to observe in order to gain access and obtain permission to conduct trials. Whilst this implies that district authorities and community leaders command significant control it is also important to remember that researchers possess significant leverage since trials are generally well resourced and more often initiated and directed by researchers. In Saradidi these questions did not feature to the same extent since, in keeping with the participatory ethos of the health and development programme, the locus of control already lay with local residents. International

researchers were invited by community leaders to support the programme and they worked in close partnership with national mentors. Research was viewed as a core component of the health projects and the primary aim of research activities was to help the programme to achieve its goal of improved health for local residents. The fact that research operated within a locally developed and managed infrastructure helped to address any potential barriers or perceptions of disconnect between researchers and the public. The direction of interactions was two-way and researchers were accountable to the local programme board.

A gradual shift occurred in the 1990s when KEMRI/CDC started to conduct large externally-funded trials which prioritised research outcomes rather than the delivery of healthcare. These trials required a different type of infrastructure and no longer operated within or alongside rural health projects. The intensification of research and the development of the HDSS directly affected how control was exercised. Pre-existing nyamreche or community health workers became facilitators of research rather than agents of change and communities became hosts rather than co-initiators of research. This, coupled with the advanced technology associated with clinical trials, expatriate leadership and the CDC logo on a fleet of vehicles fuelled the perception within communities of research emanating from 'elsewhere'.

The research agenda was now mainly driven by scientists based at the expanding research facilities on the outskirts of Kisumu. These scientists worked closely with local field workers; however they were primarily accountable to external sponsors, ethics committees and regulators. This meant that community members living in the areas where studies were taking place were no longer actively involved in initial or ongoing decision-making about research. This disconnection resulted in incidences of community resistance, a form of passive control, and contributed to rumours which have been described as a symptom of a potentially problematic relationship between community and researchers (Geissler and Pool, 2006b). Researchers recognised that they had to start to do more than just observe inherent 'community entry' protocols in order to secure ongoing community acceptance and meet recruitment targets. To this end existing and new staff were delegated specific responsibilities for strengthening community relations, managing VRs and developing new ways of involving community members in discussions about research.



Thus within the period of 30 years the KEMRI/CDC research programme in Nyanza Province has evolved from early involvement in local community-led health programmes into a global enterprise. Moreover, while science was an intrinsic part of the Saradidi community health and development programme from 1979 to 1989 currently the scientific component is more externally applied and therefore separate from the community. This disjuncture is explicitly evident in community members' initial responses and recurring misgivings about the HDSS. The notion of community has also changed. Whereas once the community was a resource or the source of change, now it is portrayed as a potential problem and a crucial partner.

In practice this gradual but marked evolution has meant that researchers have had to learn how to make a place for science in settings where encounters between scientists and their lay and professional public is overlaid by differential access to resources, technologies and expertise. This too has driven the need to focus even more attention on CE. Comparing the structure of community relations between 1979 and not, it is evident that CE today is very different. Because of the external origin of both studies and the science involved, CE today is much more about researchers reaching out to communities rather than the two meeting as partners on an equal footing.

## **Chapter 5:**

# **The Framing of Community Engagement at KEMRI/CDC**

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*'The community are those that seek our services, those whom our activities affect out there in the field, and even where our infrastructure is situated, and the people we interface with on a daily basis as we do our work'*

***Senior Kenyan Scientist***

## **Introduction**

This chapter examines how community engagement (CE) is framed and organised at KEMRI/CDC. To do this I firstly provide an overview of the organisation of CE, conduct a review of the terms of practice, give an account of the personnel involved and outline the main methods used in CE. Secondly I consider how researchers' cultural and social conceptions and assumptions about the local community shape CE and serve to demarcate a boundary between the practice of research and the place where research is conducted.

The empirical data for this chapter are drawn from a wide range of sources including interviews and informal conversations with researchers, VRs, CAB members and community members, observation recorded in my field notes and source documents. My fieldwork primarily focussed on the rotavirus vaccine trial (RVT) and the malaria vaccine trial (MVT) so most of the social situations I use to illustrate points relate to these trials. However during the course of my fieldwork I also gained insights into core issues of relevance to the practice of CE which apply across the KEMRI/CDC programme. These pertain to the distinction made by KEMRI/CDC personnel between the research community and the community where health research takes place, and the understanding of CE as a mode of interaction between these communities.

In terms of sequencing, this chapter complements the historical review narrated in chapter 3. Specifically it seeks to describe how researchers are currently engaging the 'community' in projects which promise access to medical technologies, such as childhood vaccines which could, if proven effective, reduce mortality and morbidity against prevalent diseases. It also explores some of the drivers for CE and some of the challenges and complexities encountered in CE. Not least amongst these are defining the practice of CE, and delineating what constitutes the 'community', and accounting for the norms and values of this community.

## **Organisational Construction of Community Engagement**

In this section I explore the main terms of practice which are applied at KEMRI/CDC to describe the 'community' and community relations. I also consider the relationship between ethics and CE from the perspective of researchers. Then I provide an overview of the personnel involved in CE and their respective roles. Finally I outline the range of strategies which are used at KEMRI/CDC to engage defined groups within the community.

## **Terms of Practice Applied in Community Relations**

Several terms are used to describe community relations in the KEMRI/CDC setting: '*community liaison*', '*community entry*' and more recently '*community engagement*'. A standard operating procedure (SOP) drafted in 2010 by the community liaison officer (CLO) with the support of quality assurance officers and others actively involved in community relations provides some insights into the subtle differences in how these terms are applied (see Appendix II, Doc. 2). The term '*community liaison*' appears in titles and job descriptions, and it conveys a notion of structure and organisation; for example there is a community liaison officer and a community liaison office. The term '*community entry*' on the other hand is synonymous with the steps taken by researchers to negotiate access and obtain permission to conduct research in specific communities. The CE SOP suggests that '*community entry lays the foundations for ongoing partnerships with key respected persons who represent the needs, concerns and wishes of the targeted community*'. The document goes on to emphasise the importance of continuing dialogue with these partners

in order to *'maintain community engagement prior to and during the course of a study'*. Hence in contrast with *'community entry'*, *'community engagement'* is understood to represent longer term and more participatory interactions between researchers, community leaders and community members.

The CE SOP provides less insight into how the concept of *'community'* is understood and defined at KEMRI/CDC. It uses the terms *'the targeted community'* and *'research community'* and lists individuals and groups of people who live in or have a link to the areas where trials are conducted. To reflect further on this I have synthesised the main points from KEMRI/CDC personnel's definitions and interpretations of *'community'* and related *'community engagement'*.

Two central ideas were communicated about what constitutes a *'community'*: firstly the *'community'* is the *'place where we do this work'*; and secondly the *'community'* represents the *'people we interface with in the course of our work'*. Who these people are varies depending on the interviewees' positions and frame of duties. For example an American trial investigator described how for her the *'community goes on and on'* (RS 13) from trial participants, their families, those who live around them, right up to those responsible for national malaria control. In contrast those responsible for data collection in the field applied a tighter frame.

*'Ok, me when I just hear of the community the first thing that comes in to my mind is the people that I visit or that the community interviewer visits, the people that I keep on knocking on their doors, compounds day in day out to solicit for information irrespective of the source exactly, so they are just the villagers, exactly.'*

*Male Fieldworker, RS 07*

Staff members' thinking about *'community'* was characterised by a differentiation between researchers and the general community. This distinction featured less amongst staff living in the areas where research was taking place, but even they described how the tools of their trade, bicycles and motorbikes, and their duties set them apart from their local community. Researchers based in clinics and hospital facilities and those responsible for collaborating

with Ministry of Health (MOH) counterparts also distinguished between the MOH community and the local community.

*'I guess I just think of it, I don't know, the place where we do this, so Siaya, you know, then I guess I think of it as the Ministry of Health community, I guess I think of it in those two ways. Sort of the [so you see kind of almost different communities out there?], yeah, so when I think about who needs to know, you know it is the local community around the area where we are going to do it, it is the hospital community, it is the Ministry of Health community, then it is like the KEMRI/CDC community, people have to be informed, [and the government administration would that come under the local community?], yeah I guess I would, like the chiefs and all that I would put under the local community.'*

*Senior American Scientist, RS 14*

The above quotation captures explicitly the strong undertone of *'those who need to know'*, an undertone which shaped many staff members' interpretations of *'community'* and related *'community engagement'*. The *'community'* constitutes those who need to know about KEMRI/CDC research programme; those who participate or seek our services, those who live where we work, community leaders and official collaborators and who shape public opinion.

Whilst the CE SOP (Appendix II, Doc. 2) does not explicitly define the term *'community'*, it includes a chart which differentiates between three main channels which should be used to facilitate *'community entry'* during preparations for KEMRI/CDC studies. In this chart individuals and groups are categorized under three headings: *'Provincial Administration'*, *'MOH and other Partners'*, and *'General Public'*. The latter is used as a term to denote everyone else who lives in the area where KEMRI/CDC research is taking place. Conceptually this chart represents how the *'community'* is imagined as constituting distinct groups. It contains a comprehensive list of individuals and groups but no further elaboration on how interactions with stakeholders from these channels should be framed. This may be because it can be difficult to convey practical and tacit knowledge in formal documents. This omission also serves to emphasize that documentation provides an incomplete picture of the practice of *'community engagement'* or the understanding of *'community'*, which are

significantly influenced by the personalities, backgrounds and expectations of the primary players both within KEMRI/CDC and outside.

The Kenyan staff member responsible for 'community liaison' in the RVT and MVT depicts community engagement' as a 'learning process' - an art rather than a science. Each trial has different features therefore it is difficult to apply a single model across the research programme. The approach to CE also has to be adapted in response to questions raised at community level, or bottlenecks experienced in the course of different trials. She described these as 'opportunities' to evaluate practice and commented on the difficulties of conveying experiential knowledge in SOPs and guidelines.

*'But I think the more positive thing, the positive things about it, you see like, it's also like a learning process we really don't have like everything on paper, so such opportunities also make you think like what should we do better [laughter] [yeah].'*

*Female CLVT, RS 11*

In our interview the Community Liaison for Vaccine Trials (CLVT) employed the metaphor of a 'tool box' of methods which can be used to engage the community. She distinguished between a core strategy which applied conventional tools, such as barazas (open community meetings facilitated by administrative chiefs), engaging opinion leaders and working with VRs and CAB members; and an evolving strategy which was responsive to concerns raised in the course of trials and helped to devise new methods.

*"I would confidently say that before, the strategy that we had was more like engaging the opinion leaders, the barazas the CAB and the VRs, but I think like also like having a problem or a concern raised in the community would also make you think of another strategy (to use) to turn out... a good example like was using the churches to pass the information across. That didn't come up until we had an experience in Ng'iya, then realizing like maybe fathers are not willing to participate or are not willing to have their children participate in the studies then you again think like how do we get these fathers, then the boda-boda issue came up. Then it also depends on the targeted group for example like Tuberculosis if think about it, the adolescent cohort, then you would think of involving schools, but you think of maybe Rotavirus, malaria that the age group is young, then you think of maybe involving women groups so I think it also like depends on the study orientation."*

*Female CLVT, RS 11*

In essence 'community engagement' is understood to be the process of 'a research community interacting with another community'. Researchers assume responsibility for ensuring that community members know who they are, what they are doing and what involvement in research entails. The emphasis is on communication, sharing information, encouraging participation, gaining support and fostering a sense of community ownership or responsibility for the research programme. 'Community engagement' is also viewed as a means of dialogue and exchange which can help shape how research is conducted and address community concerns. A few people also talked about how 'community engagement' can provide a forum for discussing mutual benefits and the ways in which research can contribute to community development.

### **The Relationship between CE and Ethics**

KEMRI/CDC staff members' interpretations of ethics included reference to externally applied ethics constructs, such as Good Clinical Practice (GCP) (International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use, 1996a)<sup>4</sup>, professional codes of conduct and personal and community values premised on cultural norms and practices. GCP compliance was understood to drive the conduct of research with its emphasis on quality, safety, documentation and demonstrating respect for participants' rights. KEMRI/CDC personnel viewed GCP as something researchers have to abide by which is not of direct relevance to CE. In fact a case was made for ethics training to branch out and include more deliberation about the norms and values of researched communities.

*'...the training we receive is basically... on how to do proper documentation, how to do good informed consent, how to fill out case report forms, report SAE's you know safety procedures and all that... But for me I would think ethics needs to go beyond that because there is that aspect of ethics in GCP which is good but now there is, you know, normative you know whatever, normative values of people which is also an ethical issue that needs also some kind of training which kind of has been neglected in the training, because, because the training that is done is just purely GCP.'*

*Male Fieldworker, RS 02*

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<sup>4</sup> Good clinical practice is a set of internationally recognised ethical and scientific quality requirements which must be observed for designing, conducting, recording and reporting clinical trials that involve the participation of human subjects.

The exchange of information between researchers and community members associated with CE was presented as a way of learning how to best apply a research protocol within a given community. GCP focuses on compliance with international standards whereas CE promotes an understanding of what is acceptable in the cultural context of operation and where conflicts may arise. Acceptability was talked about in terms of people's dignity and respect for their personal and community norms and values. Importance was also placed on transparency about the intentions and purpose of research and the need to account for community members' sphere of experience and related understanding.

### **Synopsis of Terms**

This overview of the terms presents 'community engagement' as the way in which researchers interact with the researched community in order to raise awareness about their work and be responsive to issues which arise in the course of trials. CE helps researchers learn how to apply research protocols with due consideration of cultural norms and values. The use of the term 'community engagement' at KEMRI/CDC over the last 5 years reflects the perceived need to strengthen relationships and form partnerships with people who represent the communities where research is taking place. Chapter 3 described the shift from 'community entry' to 'community engagement' in more detail and underlined its significance for the ongoing success of the KEMRI/CDC research programme. Researchers believe that they have to be proactive about reaching out to 'those who need to know' and have tasked individuals with specific responsibility to ensure that CE is core to the KEMRI/CDC research programme.



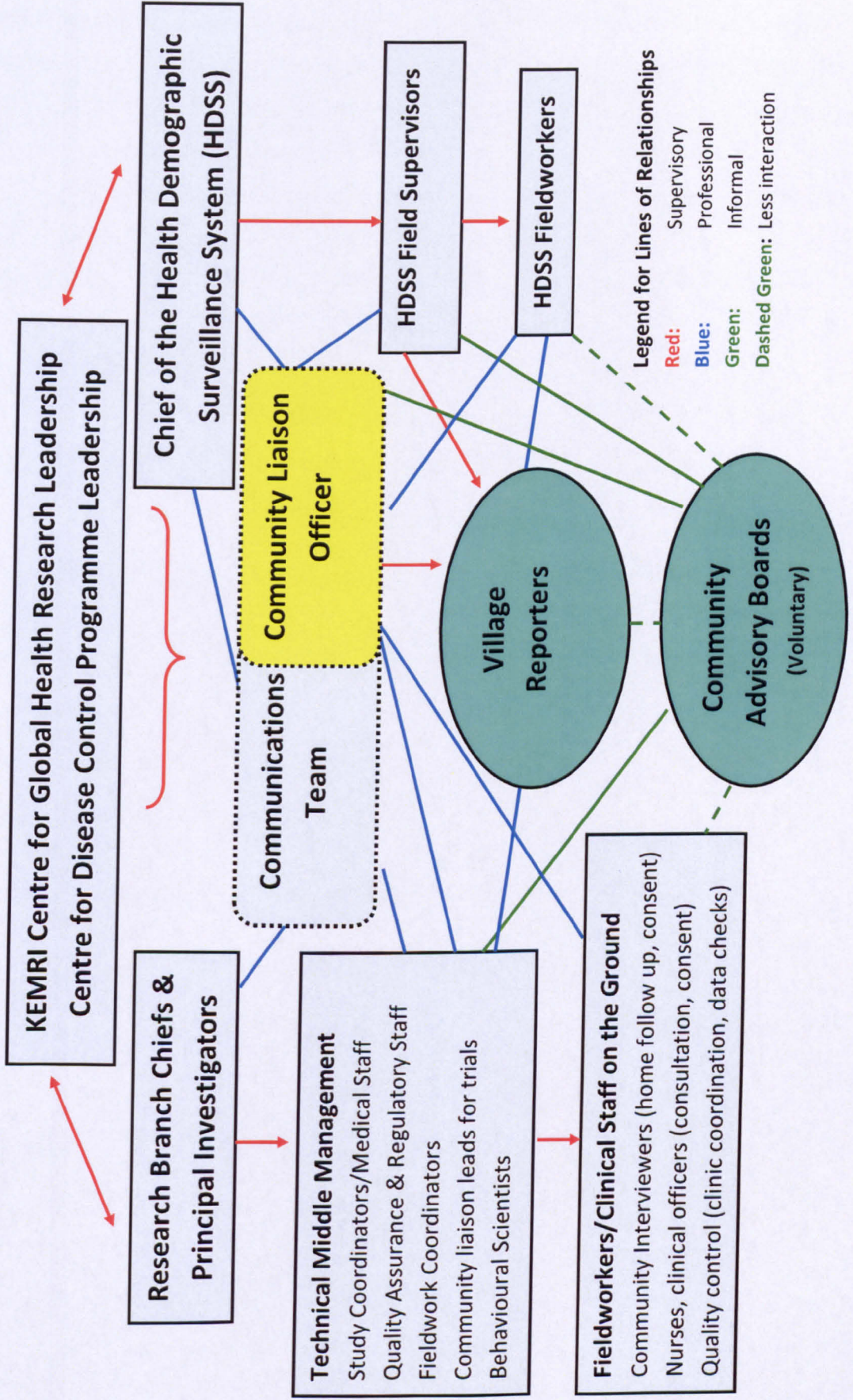
## Personnel: Roles & Relationships

Here I provide an overview of all those involved in CE at KEMRI/CDC. In chapter 5 I will expand on the perspectives and experiences of key personnel in order to shed light on pertinent questions, challenges and opportunities encountered in the practice of CE. My objective here is to depict the organisational structure and the different means of CE applied at KEMRI/CDC.

Figure 2 below depicts the primary players involved in CE at KEMRI/CDC and illustrates their respective interrelationships. Table 2 below provides an overview of the qualifications required for paid positions and outlines the related working conditions. Whilst overall responsibility for the coordination of CE lies with the CLO (highlighted in yellow) it is evident that many others play a significant role in shaping community interactions. Particularly important are FWs who collect data at community level and those who have been delegated study-specific community liaison duties by their line managers. The support, vision and visibility of the KEMRI Centre for Global Health Research (CGHR) Director and the CDC Director also influence practice, as do decisions taken by research branch chiefs, principal investigators and study coordinators about trial logistics, the involvement of local collaborators and the recruitment and follow-up of participants. The recently formed communications team also supports CE by providing materials which can be used to facilitate information exchange at community level. To quote a senior American scientist (RS 14) *'...everyone plays a role, but the CLO most formally'*.

Figure 2 includes village VRs and CABs since they play an active role in facilitating the KEMRI/CDC research programme. Their respective shapes and lines of relationship with personnel at KEMRI/CDC are marked in green to differentiate the more informal nature of these relationships from the formal lines of accountability which exist between members of staff. I provide some detail about VRs and CABs when I outline the main means of CE applied at KEMRI/CDC, but I will expand more fully on their roles in chapters 7 and 8.

Figure 2: Personnel & Community Intermediaries Involved in CE at KEMRI/CDC



**Table 2: Working Conditions & Stipulated Qualifications for Paid Jobs at KEMRI/CDC**

Positions	Qualifications Required	Working Conditions
CDC Director	PhD or similar, publications track record, direct hire from USA	Housing, Diplomatic Passport, 5 year renewable contract
CDC Senior Scientists (including branch directors)	MD, PhD or similar, publications track record, Direct hire from USA	Housing, Diplomatic Passports Renewable contracts
KEMRI Director	PhD or similar, good publications track record, extensive experience	Long term contract, government position, security and pension
KEMRI Senior Scientists (including brand directors)	Masters or PhD, publications record, relevant professional and technical experience	Salary determined by qualifications & length of service, government positions, pension
International Scientists	Depends on the job, qualifications, professional expertise which is not readily available in country	Contracts are negotiated, some are paid as consultants
Technical Middle Management: Study Coordinators Fieldwork Coordinators Clinicians with management duties Regulatory Staff Quality control staff in the field Community liaison leads for trials Behavioural or Social Scientists	Bachelors degree, or a relevant medical or nursing qualification, professional expertise and experience	Annual renewable contract Salary scale determined by level of qualifications and length of service, pension contributions are payable at the end of the year
Clinical Research Staff working in the field, at clinics and hospitals where the trial are taking place	Nationally recognised nursing or medical qualification, professional experience and expertise.	Annual renewable contract Salary scale determined by qualifications and length of service, pension contributions are payable at the end of the year, no fixed pension or job security
Fieldworkers	Form 4 Leavers with good grades (Last year in secondary school), resident in area where research taking place, speak Dholuo	Yearly renewable contracts Locally competitive salary
Village Reporters	Resident in area where research taking place, respected locally, able to read and write (in English), basic knowledge in public health, willing and ready to work	Casual staff paid set hourly or daily rates for delegated tasks and meetings

## **Means of Engagement**

Here I describe the different means of engagement which are used by KEMRI/CDC personnel to interact with the 3 community channels cited in the CE SOP. These are the 'Provincial Administration', the 'MOH and other Partners', and the 'General Public' (i.e. applied as a container for everyone else). The nature and format of interactions between respective representatives will be expanded on in more detail in subsequent chapters.

### **1. Provincial Administration**

The provincial administration channel ranges from the Provincial Commissioner down to chiefs and village elders. At senior level collaboration mainly consists of official communiqués and occasional formal meetings between KEMRI/CDC directors and the head of the provincial administration. Previously interactions at district level mainly targeted chiefs. More recently increased attention has been paid to improving communication between the district officials and KEMRI/CDC staff operating in their areas. The CLO now provides the district commissioner (DC) with monthly updates and attends relevant district level meetings. Chiefs are still viewed as important gatekeepers and accordingly receive training about some trials and attend an annual meeting at the main KEMRI/CDC offices.

### **2. Ministry of Health and other Partners**

This channel includes the provincial and district directors of medical services and public health, the district health management team (DHMT), health facility committees and non-governmental and community-based organisations that provide health services. Collaboration with high level government officials is mainly the premise of the KEMRI/CDC directors and senior investigators and comprises formal meetings to draft memoranda of understanding. These types of agreements are also drawn up between health facility committees and KEMRI/CDC with the assistance of trial managers. Researchers also meet regularly with the DHMT, and collaborators who provide significant clinical oversight are sometimes included as co-investigators on research protocols. Relationships between research and regular staff members within clinical settings are less formal and are influenced by lines of accountability, communication, work load, organisational culture, and access to resources. At district level researchers are required to attend quarterly health stakeholder forums which are chaired by the DC and organised by representatives from the

ministries of medical services and public health and sanitation. These forums aim to strengthen accountability and improve communication between community leaders, government and non-government health service providers. They were introduced in 2008 as a governmental initiative to seek to respond to and coordinate the growth of non-governmental organisations and research groups active in the district.

### **3. General Public**

The term 'General Public' is used in the CE SOP as a way of capturing everyone who lives in the places where research is being conducted. It refers to the constituents of the 'local community' and indeed this may be a more apt term for what is meant here. For the purpose of this outline I will differentiate between CE activities which target parents of potential participants and those which target the whole local community. I also provide a brief outline of the role of two key community intermediaries - VRs and CAB members - in these kinds of interactions.

#### **I. Village Reporters**

Designated village members have been involved in the implementation of research since the start of the KEMRI/CDC collaboration in 1979. They have been particularly valued as a means of creating inroads for researchers because they are trusted by other community members. The term 'village reporters' was applied to this group when the Health Demographic Surveillance System (HDSS) was established in 2001. A VR is essentially an individual selected by the community members after meeting specified criteria (*'be respected members of the community, be able to read and write in English, have a basic knowledge of public health, be willing and ready to work'*) to support the implementation of KEMRI/CDC projects and studies. They are casual employees who perform delegated duties for the HDSS and *'are engaged by projects on a need basis'* (VR SOP-Appendix II, Doc 3). VRs are viewed as central to CE and work closely with community liaison staff and facilitate information exchange about KEMRI/CDC projects at household and village level. They are described by the CLO as *'the interface of KEMRI/CDC at village level'* and are expected to represent the work of KEMRI/CDC in their villages. Whether this equates with a more anthropological understanding of 'embodiment' is debatable since to all intents and

purposes VR's immediate bond is to their home and their land. However they carry their material symbols of belonging to KEMRI/CDC proudly.



**Photo 8: Informal Discussion after a VR Meeting**

## **II. Community Advisory Boards**

CABs are a more recent form of community representation at KEMRI/CDC. The first CAB was set up in 2004 and now there are 4 CABs functioning in the main areas where KEMRI/CDC conducts research (Kisumu, Asembo, Gem and Karemo). CAB members are nominated by community members and represent a broad cross-section of the local population. Their mandate is to *'foster partnership between KEMRI/CDC research teams and the local communities participating in KEMRI/CDC conducted studies to benefit advancement of research and the community'*. They are asked to advise researchers on how to approach certain issues and to provide them with feedback about communities' views and understanding of research. They are not supposed to mobilise communities for participation but rather to act as a resource body within their locations. This involves facilitating connections and organising exchanges between community-based organisations and community liaison staff. CABs meet quarterly and their agenda generally includes updates on KEMRI/CDC activities, overviews of new trials and feedback from CAB members about

community perspectives. These meetings are attended by study coordinators or field supervisors for the HDSS which means that there is limited interaction between CAB members and FWs. Indeed there is limited opportunity for VRs and CAB members to meet in a formal capacity. As a result they tend to work in isolation and not know much about each others' duties and responsibilities as regards CE.



**Photo 9: The Kisumu CAB (mainly serves the HIV Research Branch)**

### **Activities targeted at the general public or 'local community'**

These activities involve presenting information about KEMRI/CDC research at community forums. Meetings can be open to all (as is the case of barazas) or can be restricted to members of specific groups or professions. The nature of the meeting determines the content of the presentation and the seniority of staff who attend.

- Barazas organised, called and chaired by chiefs and assistant chiefs
- Village gatherings organised by village elders
- Presentations at church services and meetings
- Talks/oral presentations at community-based organisations & women's groups meetings
- Formal presentations at forums for head teachers, opinion leaders and local politicians

Chief's and assistant chief's barazas were the primary venues for public contact between community members and representatives from KEMRI/CDC. Barazas are open community meetings which are facilitated by a chief or an assistant chief and are attended by village elders and other community members. Barazas are the forum used by chiefs to disseminate information at community level. This information can refer to governmental policies, security, development initiatives or other local affairs. With the chief's permission individuals and representatives from various organisations or government offices can also use barazas as a means of publicizing their work, events, projects or communicating specific messages. Barazas are mainly held in the morning hours and mainly attract older women and men and some young mothers and children. Younger men are sometimes present on the periphery standing by their bicycles or motorbikes.



**Photo 11 & 12: Chief's Baraza in Siaya Town, May 2009**

Barazas take place outside a chief's offices or in a central place within a certain location. These places usually have benches, otherwise chairs are either bought from the chief's office or people bring their own. Women sit in groups apart from the men, and younger women mainly sit on the ground on lessos (colourful pieces of material which women tie over their clothes). I usually tried to sit with the women but more often I would be asked to sit at the front, facing the meeting, on chairs reserved for the chiefs and visitors. On one occasions when I did sit with the women one of my male research assistants refused to sit with me; according to cultural norms he could not sit with the women on the ground. He could stand at the back near the women but could not sit with them on the ground.



### **Activities targeted at parents/guardians of potential participants**

These activities involve more intimate discussions with parents and in particular mothers. They include oral presentations and follow-up discussions with individual mothers at health clinics, village meetings arranged by VRs and village elders, and home visits conducted by FWs and VRs.



**Photo 12: CLVT talking about the MVT before it started with a women's group**



**Photo 13: Targeted meeting with mothers to boost recruitment after start of MVT**

## **Cultural & Social Construction of the Community**

Here I consider how the way in which the 'community' is imagined, talked about and experienced by researchers demarcates a boundary between the practice of research and the place where research is conducted. Earlier in this chapter we learnt that a distinction is made by KEMRI/CDC staff between the local community where research takes place and the research community. This distinction prevails despite the fact that the majority of KEMRI/CDC's workforce originates from the local communities in which research is conducted. By joining KEMRI/CDC, local researchers obtain access into a new community and the exposure they gain from this, the tools of their trade, bicycles and motorbikes, and their duties set them apart from their local communities. This immersion into the world of science and local researchers' association with a modern project and a powerful organisation alters the way they think about the places where research is conducted. The community becomes framed as a place awash with 'cultural' beliefs and practices which are considered to be contrary to the exercise and goals of bio-medical research. Researchers cite stories about the use of traditional herbal remedies in the context of a trial, and suspicions and related rumours about study procedures which involve taking blood from research participants, as examples in case.

International and local researchers acknowledged the need to respect community norms and practices and some suggested that more attention should be paid to understanding these in the practice of CE. At the same time this willingness to engage difference did not reduce their experience of a wide gap and potential contradiction between local culture and science.

*'Of course we have the GCP ethics, ok, you know that specify the responsibility of the researchers towards the research, the researched community, there is that part of which is commonly known. But there is also something that we call normative, the norms and the morals of the society I mean of dealing with the people, like respecting their cultural beliefs and systems which at times could be conflicting to the interests of research...'*

*Male FW, RS 02*

Despite this conscious emphasis on respect for different worldviews and experiences it was also apparent that researchers viewed rumours, which often arose as a community response to trials, as weird misunderstandings or reinterpretations of their work (see chapter 9 for a detailed discussion and analysis of these and other community responses). From the researchers' perspective, the strangeness of some rumours, in particular those relating to blood, demarcated the distance between research and community, and constituted the community as an 'other' which CE has to work on. This 'other' was also sometimes construed as potentially dangerous; for example FWs talked about themselves being at risk because of rumours and associated hostility. They argued that they should go into the field in pairs or groups because of the dangers of enraged fathers or superstitious natives, and research staff required to live in the community claimed risk allowance. These points serve to illustrate that the community is seen as something which is out there, quite strange and potentially dangerous which has to be brought into contact with science by the means of CE.

Another prevailing view of the community, closely related to accounts of 'irrational' rumours, is that people out there do not understand what researchers are trying to achieve; they are not enlightened and have a limited knowledge of science. This helps to explain the emphasis placed on information exchange in CE at KEMRI/CDC. Researchers felt compelled to explain science to community members in order to overcome popular suspicions about the purpose of research and particular trial procedures. To try to bring the community on board and counteract rumours about the withdrawal and use of blood in research, researchers employed series of interventions. These included blood demonstrations, talks by mothers who had taken part in research before and research facility and laboratory visits for chiefs and CAB members.

Blood demonstrations were facilitated by community liaison team members with occasional assistance from clinical trial staff, and they took place during chiefs' and assistant chiefs' barazas. In a demonstration I observed the community liaison team members used a bottle of red-coloured water to portray the normal volume of blood found in infants. She then contrasted this with the amount of blood withdrawn from infants during study visits by extracting 2mls of the red-coloured water from the bottle. In her commentary she

transmitted other facts about blood collection and used humour and interactive methods to engage her audience. In essence the demonstration explained the scientific process of venepuncture with some reference to the reasons for taking and testing the blood. As such it helped to clarify certain issues. On rare occasions however the blood demonstrations also led to further speculation when some onlookers thought the CLVT was using human blood in her demonstration.

Another intervention used to address blood rumours in public meetings was to invite previous research participants to talk about their experiences. This idea was proposed during discussions between researchers about problems that the RVT team were facing in the field. The principal investigator (PI) of the Kisumu infant Breastfeeding Study, a trial seeking to reduce maternal-to-infant transmission of HIV, suggested that participants from his trial may be willing to help. During the course of this trial some of the mothers taking part had formed a support group and a few had become active peer supporters. The PI's suggestion was discussed with these mothers and several agreed to support the RVT team in their efforts to address community concerns about blood. These mothers were from Kisumu so they travelled with the CLVT to prearranged meetings where they shared their experiences and helped to answer questions posed by community members. According to the CLVT their contribution was very valuable and offered a more personal, accessible and credible perspective than that given by researchers.

The CAB also represented a way of overcoming boundaries and suspicions about researchers' intentions. CAB members helped researchers respond to concerns by alerting them to issues being raised in their communities, arranging forums for discussions and providing advice on who should address specific questions or rumours and how. CAB members and local chiefs were also given the opportunity to visit research facilities and laboratories. One of the main aims of these visits was to give chiefs and CABs the opportunity to see what happened with blood samples collected as part of trials. The hope was that they would then take this information back to the communities to help allay fears about what is being done to the blood. This intervention aimed at reducing the sense of distance and disconnect between the research enterprise and the local communities.

Whether these interventions did achieve a rapprochement is another question which is

central to this thesis. It is also a question which depends on how rumours and related speculations about research are understood. An extensive literature documents the history, genesis and meaning of blood rumours in relation to medical research and other interventions which represent an intrusion into African society (White, 1993, White, 1995, White, 2000, Fairhead et al., 2006b, Geissler, 2005, Geissler and Pool, 2006a, Vaughn, 1991). White (1993, 2000, 1995) draws connections between blood-stealing stories and the political and economic exploitation which occurred during colonial and post-colonial rule in East Africa. Drawing on this work Geissler and Pool (2006a) suggest that the 'blood stealing' idiom is a popular means of debating medical research and related political-economic exploitation. They describe how popular concerns about blood are a common response to medical research across the African continent, and how emerging rumours draw on local interpretations about the flow of resources and the cultural value attributed to blood. Seen in this way, rather than simply being misinterpretations of reality, rumours can embody a deeper popular critique of the distribution of the benefits of science and the boundaries which control resources in global health research. If this is the case then interventions which only elucidate practical aspects of the withdrawal and use of blood in research will not address underlying concerns about the exchange of value and unequal benefits. This observation is important to the framing and practice of CE at KEMRI/CDC, since it suggests that core questions which arise in response to bio-medical research are not always adequately discussed or dealt with in CE. The primary focus of CE in its current format is to redress practical misunderstandings communicated in popular critique rather than consider sufficiently the socio-economic context within which such criticisms are voiced.

## **Discussion of the Main Themes**

The current framing of CE at KEMRI/CDC suggests that CE is about researchers reaching out to the community where trials take place, principally by conveying information and teaching laypeople about science. The local community is in CE presented as separate from the KEMRI/CDC community and in this formulation 'community' comprises: those who need to know about the research programme; those who participate in or seek services from this programme; those who live where research is taking place; and community leaders and

official collaborators who shape public opinion. Much emphasis is placed on information exchange, transparency about the purpose of research and reaching as many people as possible. Other potentially important aspects such as employment, health service provision and infrastructure-building are less emphasised. KEMRI/CDC personnel are tasked with fostering good community relationships, and particular personnel are delegated direct responsibility for communication, collaborating with community leaders, and forming representative bodies, which can help researchers to apply protocols with reference to community norms and values.

CE is conceived of as being both a learning process and something that has to be planned carefully to mitigate possible discontent and the potential influence of cultural idioms and related blood rumours. These rumours influence researchers' thinking about the local community and further entrench boundaries and demarcations already drawn between the KEMRI/CDC community and the place where trials take place. Rumours are in and of themselves indicative of a boundary between researchers and the community and they have implications for how CE is framed and practiced. In chapter 3 we saw how the resurgence of rumour and related negative media reporting in 2004 resulted in the appointment of a CLO. In this chapter we have seen how rumour is conceived of as a threat to the research programme which must be dealt with in CE. Particular interventions are developed to overcome concerns about the withdrawal and use of blood in research. But whether these practical interventions achieve their purpose is questionable, since they emphasise practical points and arguably do not pay the necessary attention to deeper underlying concerns about unequal exchanges.

From the present organisation of community liaison at KEMRI/CDC CE appears to be conceived of mainly as a tool to achieve smooth operation of trials and to counter negative rumours and opposition; the principal means to this end are thought to be information, knowledge and increased familiarity with science.

## **Chapter 6:**

# **KEMRI/CDC Staff Perspectives on Community Engagement**

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*'...it was just winning their trust, and being honest with them, who you are, what you are doing, I am part of you we can all work as a team, we are here to help your children...'*

### ***Community Liaison for Vaccine Trials, RS 11***

## **Introduction**

This chapter considers how CE is practised and socially constructed at KEMRI/CDC. To do this I will recount the experiences of five groups of key personnel who operate at different levels of the research programme. These synopses will facilitate an analysis of the social construction of CE and shed light on important challenges and tensions encountered in the practice of CE. The empirical data for this chapter were drawn from a series of interviews with 19 researchers, informal conversations with KEMRI/CDC personnel and observations recorded in my field notes. In places I also draw on interviews with community intermediaries to illustrate particular realities.

This chapter demonstrates that the definition and application of the terms 'community' and 'CE' are fluid and are influenced greatly by individuals' spheres of activity and responsibilities. There is significant pressure to present the research programme in a positive light and to manage community relations in the best possible manner in order to achieve this end. This does not negate a participatory ethos; however, it raises questions about the overall aims and drivers for CE.

## **Social Construction of Community Engagement**

The following five synopses draw on the experience and thinking of different levels of personnel at KEMRI/CDC who are involved in CE. The aim is to facilitate a more in-depth understanding of the social construction of CE at KEMRI/CDC. I chose to focus on groups operating at different levels of the KEMRI/CDC hierarchy (see Figure 2, chapter 4) in order to capture a full breadth of perspectives.

### **Level 1:**

#### **Senior Scientists: *'The Face of the Research'***

The KEMRI/CDC public health and research collaboration programme in Nyanza province operates under the official umbrella of the KEMRI Centre for Global Health Research (CGHR). Physically the KEMRI-CGHR main office is based within a secure compound on the outskirts of Kisumu. This compound is walled and one has to pass through two gates manned by security guards to access it. Many different buildings are located within this compound; the KEMRI-CGHR main office is on the right as one passes through the second gate, the KEMRI/CDC main offices and scientific wing are housed next to these offices in a substantially larger and more modern building.

Apart from the KEMRI/CDC programme it is important to remember that the KEMRI-CGHR hosts many other research programmes with international and national universities, the Wellcome Trust and World Health Organisation. The KEMRI/CDC programme is by far the largest collaboration in terms of personnel and funding and is managed by a senior American scientist employed by CDC. A senior Kenyan scientist is the Principal Investigator (PI) of research conducted as part of this collaborative agreement (CoAg) which is funded mainly from a budget provided by CDC. Within the CoAg system an accounts department manages funds, and all expenses must be approved by the highest ranking KEMRI-CGHR scientist. KEMRI-CGHR is the official employer of all national and some international staff. The role of CDC and other partners is to provide technical support in the implementation and management of research programmes are endorsed by KEMRI-CGHR. In practice the lines of accountability are less clearly defined and, in terms of access to resources, the relationship between KEMRI-CGHR and CDC is unequal. The KEMRI-CGHR offices within the



Kisian compound are less pristine, their internet system not as reliable as that provided for staff working for KEMRI/CDC and there are very few KEMRI-CGHR vehicles. Such differentials tend not to be voiced or discussed openly between collaborators although they are of significance to the partnership.

The character and workings of the KEMRI/CDC collaboration are very important since they have a direct impact on the public perception of research programmes. They also have a bearing on how the senior scientists collaborate with colleagues and partners in the Ministry of Medical Services and Ministry of Public Health and Sanitation, the public administration, the political fraternity and other research bodies and non-governmental organisations working in public health.

Senior scientists' main responsibilities in relation to CE include ensuring that research programmes are endorsed by the relevant national and provincial level government, medical and public health officials. This requires them to follow unwritten but established protocols and to meet and communicate regularly with these bodies and officials about ongoing research and planned projects. The leading scientists from CDC and KEMRI-CGHR concur about the importance of communicating the purpose of KEMRI/CDC programmes and activities in well-defined and clear messages. However there is limited discussion about how to present the *'face of the research'* in a manner which reflects the nature of the collaboration as accurately as possible. Essentially it can appear that there is no joint agreed agenda on CE, and it is not always clear who has overall responsibility for the KEMRI/CDC research programme.

At community level there is little doubt that CDC rather than KEMRI is perceived to be the *'face of the research'*. This can be attributed to its higher visibility and perceived status. For example one chief described KEMRI as *'a place where research is done'* and another explained that it was not until CDC came that the impact of research was felt at community level. It was only then that people became aware of the purposes and benefits of research; before it had been out of their sight.

*'It has been here for a long time and you know KEMRI being a government body it couldn't expand largely in the way the CDC now is working I don't know whether it was limited because of funds problem, or maybe personnel, yeah, because they were there before, but*

*we could not hear them in a wide way, the way we are now getting the CDC people coming and meeting people, interacting with our community'.*

*Male Chief, CR 41*

Administrative leaders are aware that KEMRI is part of this expansion. The general public however tends to have a different perspective as a chief who is also a CAB member in Karemo Division shared with me. He explained that *'when you talk about KEMRI/CDC people like taking the last one CDC'* so I asked him to tell me what they say about CDC.

*'What they say, is that the CDC is involving about treatment, and also what (has helped) most is that like CDC, when it came in operation in the village, most of the school leavers were really involved in employment, so that one also raised people's knowing the activities, people scrambling for the jobs. You know, the job opportunities are less, so they see that CDC has assisted the community by employing their children and that is a reality. And that's what they feel good about CDC. They don't talk about KEMRI employing but they talk about CDC employing, because KEMRI is silent somehow to them, you know, when the CDC start coming to the ground they say KEMRI/CDC but the last word people grab is CDC'.*

*Male Chief & CAB Member, CR 5*

This quotation suggests that community members pay more attention to CDC than KEMRI. Both social and physical factors contribute to this, for example the status conferred by employment with an international programme and the observation by a CAB member that *'most vehicles that run around here are written CDC'* (vehicles used in the field at the time of my fieldwork only displayed the CDC logo-this changed in 2011/12 and now most vehicles display a KEMRI/CDC logo). In relation to KEMRI it is rare for a staff member to introduce himself or herself as a KEMRI/CDC employee. Instead they tend to say *'I am with CDC'*. A district official also pointed out to me that the origin of the funding and the nationality of senior technical personnel help to explain why awareness of CDC is more pronounced at community level and why people tend to view research as something foreign.

On the ground CDC is also often mistaken for a non-governmental organisation due to the free treatment and good care provided to trial participants and its programmatic work in supporting HIV care and treatment across Nyanza Province. Through the Global AIDS

Programme, which is financed by the US Government, CDC provides anti-retroviral drugs, funding, training and supervision of support centre staff. Another factor which contributes to these perceptions is that senior KEMRI-CGHR scientists do not attend health stakeholder meetings or other formal public functions as often as do senior CDC scientists. The following quotation illustrates the importance that one of the senior CDC scientists placed on being known by people based in the communities where research is taking place.

*'But also, for example, at the chiefs' day when that chief said this is doctor "do you know" whatever, which was you know kind of funny but to me the message there, to me what I liked was that he knew me [uhum] and that meant that what he was saying was that he knew me I had been out there.'*

*Senior American Scientist, RS 14*

The scientist was recollecting the time when a chief publicly referred to her as, '*Dr. Do you know*', at an annual chiefs' day which took place at the KEMRI/CDC main offices. By using this turn of phrase the chief was alluding to the fact that this scientist frequently challenges people at public meetings to take an HIV test in order to know their status - i.e. do you know your HIV status? He made this remark in a positive manner and it was evident that he valued the scientists' interaction and presence at public forums. It does not necessarily follow that chiefs and other community leaders expect the same level of interaction from the KEMRI- CGHR leadership. In fact even though the highest ranking scientist is not as well known in person at district level he possesses inherent status by virtue of his governmental position. Nevertheless the differentials in interaction do contribute to the general perception that CDC is the '*face of the research*' rather than KEMRI.

From KEMRI's perspective this has repercussions since its senior staff members believe that if CE is done the right way the studies will be owned by 'them' and the 'community'. The KEMRI-CGHR leadership also voiced some hesitation about CDC's intensive interactions with community leaders because it can lead to expectations which extend beyond KEMRI's mandate. Of particular interest is what is meant by 'we' and 'them', how collaborators refer to joint endeavours, and who takes credit for outcomes or shoulders responsibility for failure. So whilst there is general support for forums which encourage discussion and

disseminate results there are questions about how CE might more accurately reflect the nature of the collaboration and the *'face of the research'*. This synopsis suggests that the practice of CE implicitly communicates something about the social organisation of science rather than just the nature and purpose of science.

## **Level 2:**

### **Community Liaison Staff: *'Relationships, Marketing and Image'***

A Kenyan community liaison officer (CLO) coordinates community interactions across the 6 geographic areas where KEMRI/CDC undertakes research in Nyanza province. His responsibilities include overseeing the work of the VRs, working with CABs, attending barazas and stakeholder events, and meeting regularly with government officials and local politicians in order to update them on the KEMRI/CDC research programme. In addition he facilitates the annual chiefs' day at the KEMRI/CDC field station during which chiefs receive updates on KEMRI/CDC activities, interact with senior researchers and visit research facilities and laboratories. As the central resource person he organises crosscutting events which are not limited to individual trials and works closely with principal investigators, project managers, study coordinators and other staff in planning trial-related CE activities. The CLO's main remit is to represent the broader programme. Consequently he is less involved in the implementation of trial-specific CE activities which tend to be facilitated by study coordinators, field supervisors or other designated team members. In the RVT a female member of the study team was assigned these duties. An American project manager reasoned that her status as a *'mama'* and her background in teaching home economics allowed her *'to come alongside mothers easily'*. I refer to this person as the 'Community Liaison for Vaccine Trials' (CLVT) since she continued to be responsible for CE in the MVT.

The CLVT was actively involved in establishing a CAB for the RVT, and as a result she has developed a close working relationship with members of this CAB, which now serves all studies taking place in Karemo. Her other duties include creating awareness about the trials at community level, liaising closely with VRs who disseminate information at household level and maintaining good relations with chiefs and other community leaders. In the RVT

the CLVT also conducted home visits to address concerns which had arisen within the household or to follow-up infants who had defaulted from HIV care and treatment services or needed nutritional support.

The CLO and the CLVT present themselves as alternative public intermediaries between the community and the research institution. The nature of their interactions differs in significant ways. Broadly speaking the CLO represents KEMRI/CDC at a political level whereas the CLVT has closer contact with the general public and focuses on individual trials. These differences in roles may help to explain why one emphasises the importance of promoting a positive image, while the other stressed the value of rapport and gaining community members' trust. The CLO was keen to present how KEMRI/CDC is making a difference on the ground. For example, he described an initiative by which funds are set aside to demonstrate KEMRI/CDC's commitment to social responsibility. He likened this initiative to charitable activities undertaken by large commercial enterprises - thus introducing a marketing logic to the practice of CE. In practice many of these social responsibility activities rely on KEMRI/CDC staff contributing financially to support school outreach events e.g. in the form of prizes for drawing competitions. By contrast the CLO tended to stress that presentation the CLVT focused much more on establishing relationships which encouraged mutual understanding and joint reasoning.

*'Ok, my role basically is to promote the organization's positive image at community level, to generate community support and acceptance for our activities. I also play the role of being the spokesperson for the organization at community level. If projects have issues that they want to be disseminated in the community, I go down with the message properly packed that befits that particular audience, target audience, if there are issues arising from the communities like some legitimate concerns, their views, their feelings, their discomforts, their compliments about our activities, I also capture this and report back to the KEMRI/CDC management team. So I interface between the community and the organization, if there are issues or rumours, falsehoods, propaganda that also might emanate from our activities I have a plan, a rapid plan, response plan we mobilize our team on the ground and put the facts as they are, normally there are issues that the community, you know, issues of employment that keeps on recurring, issues of blood, you know so we go ahead and de-stigmatize.'*

*Male CLO, RS 01*

*'...like you get to know your audience best and then from there you can judge how do I need to address these people, how long should I need to talk to them, so like lowering yourself to their standard in the sense that you don't really make them feel like you are this level and they are this level, but like we can all reason together and work together [so not like you were the graduate] of course like fine I am from KEMRI/CDC but when I come to the community we are all at the same level so I think just [is that a matter of how you speak to them or is it a matter of attitude?] Ok, it's how you speak to them plus attitude, then time consciousness is one things I also really try as much as I can, because I realize like you tell them for example like I want to talk to you people at maybe 9am and you arrive there at 11, it is also respecting their time, respecting them, then I think slowly you build trust and you work very well with them.'*

*Female CLVT, RS 11*

The gender and personal strengths of the CLO and the CLVT played an important role in the division of their duties and the ways in which they approached their work. The CLO's gender and credentials allowed him to negotiate political and official forums with relative ease. On the other hand his position, responsibilities and gender all limited the level of interaction he had with community members, in particular mothers of trial participants. The CLVT in contrast was more able to come alongside the latter but had to put more effort into gaining the respect of local leaders. When presenting at barazas she found herself having to provide details on her marital status in order to establish her credentials. Over time, she believed she had succeeded in developing a good working relationship with chiefs and other local leaders.

In terms of challenges relating to CE, both interviewees referred to different types of pressures that they experienced in the course of their work. The CLO described some of the problems he faced in trying to maintain regular contact and positive relationships with a growing number of stakeholders. Traditionally chiefs have been the primary focus of interaction. However the expansion of the KEMRI/CDC programme has resulted in increased demands for inclusion and accountability. For the CLVT *'the main challenge maybe to use one word, is at times the pressure you get from the community [pressure] pressure'*. In this interview she was mainly talking about demands brought to her by VRs. The VRs were disgruntled about their limited involvement in the MVT and were saying *'you know the community liaison yes, she's refused to pay us'*. In fact, although she found herself having to

manage VRs' complaints, the decisions about their involvement had not been her responsibility. Moreover she had been keen to engage their help in recruitment and was apprehensive that their non-involvement and possible indifference could have a negative impact on the trial.

In my fieldwork it was evident that both the CLO and the CLVT attributed much value to CE as a means of promoting dialogue. Questions arose however about whether CE activities always succeed in providing equal opportunity for expression. The following quotation illustrates how the researchers' perspective can be prioritised even when the purported aim is to encourage involvement.

*'Community engagement simply means community involvement [which means?] which means dialogue, meaningful, ongoing dialogue with the community. I am talking, you know, engagement means the research community talking freely, without fear of reprisal or intimidation, with the community, telling the community why they must be researched, how they will be researched, timelines, the outcome, the likely outcome, their benefits, you know, the risks involved, you know, and then the feedback process, so you engage, you are with the community, you work with the community.'*

*Male CLO, RS 01*

The above quotation frames CE as virtually a one-way street for the flow of information from researchers to the community. By contrast the CLVT repeatedly stressed that CE is not just a one-off event but an ongoing process which allows one to draw on different sources to learn about community concerns. She illustrated the latter by describing how the RVT team became aware of community misunderstandings about the travel reimbursement given to trial participants' mothers. The participants themselves expressed some misgivings, the VRs and CAB members recounted circulating suspicions about this payment and even health professionals at the clinics began to question the purpose of reimbursement. People simply were not used to being paid to attend a health centre. As a result they became suspicious about researchers' motives, particularly in relation to the collection of body fluids (blood and stool). The CLVT used this example to illustrate the variability that can exist between what is ethical and what is culturally acceptable. So, whilst travel reimbursement is generally considered to be an acceptable practice within a research ethics framework, in the

specific community where the trial was taking place it was not viewed as culturally acceptable. From this scenario we learn how CE can serve as vehicle for voicing and discussing diverse perspectives, promoting mutual understanding and familiarising community members with research practices.

### **Level 3:**

#### **Communications Team:           *'Making benefits explicit'***

In October 2007 KEMRI/CDC appointed a Kenyan communications officer (CO) to strengthen internal and external communication across all research programmes. Initially she worked alongside an American communication specialist who had been sent from the CDC offices in Atlanta to support the development of this work. She was also joined by an American publications officer based at KEMRI/CDC who produced materials for the intranet and scientific posters. Since 2007 this communications team (CT) expanded to include a media specialist, a web designer, an administrative assistant and a series of interns. When it comes to CE the communications team and community liaison personnel are viewed by KEMRI/CDC as working together to achieve the same aim, albeit by different and complementary means. The latter prioritises face-to-face dialogue while the former uses various written, visual or oral media in order to facilitate information exchange.

The CT's main strategy is to produce a wide range of publications including newsletters, informational leaflets, photographs and film clips to be used in CE activities. The publications are edited and mainly written by members of the CT although contributions from other members of staff are encouraged. In addition to this work the CT also supports community events such as the annual chiefs' day, dissemination of results meetings, and activities organised to mark World Malaria, World AIDS and World Tuberculosis days.

Where the CT becomes more involved in face-to-face interactions is in media relations. Over recent years the CDC field station director had placed significant emphasis on promoting constructive relationships between KEMRI/CDC and the local and national media. The CO has been responsible for developing a more proactive stance. This has involved developing



closer relationships with journalists, providing the press with up-to-date and timely information about KEMRI/CDC programmes and helping staff respond to press enquiries. The CT runs regular media training for senior staff members and some research collaborators. This training is aimed at helping participants to manage media attention, communicate clear and well defined messages effectively and present themselves and their work in a positive light.

In relation to community liaison the CO described her main role as facilitating information exchange by presenting science in a way that is accessible to lay people. She viewed CE *'as a process of interacting with the community, whereby they learn more about our programmes and are encouraged to participate, and we receive feedback about our work'*. The CO placed particular emphasis on the feedback angle and thought that more should be done to strengthen this aspect of CE. One of her American CT colleagues presented a slightly different interpretation of CE. He explained that CDC has an agenda when it is going into a community and therefore it has to think about how best to accommodate the community in order for the community to accommodate it. Implicit in this framing of CE is the question of benefits which the CO also commented on extensively in terms of how to communicate the purpose of science effectively. She argued that people need to see and understand how trials and demographic surveillance can make a difference to their daily experience. In the following quotation the CO contrasted a vaccine trial with a development project in order to illustrate how research can be experienced as something that is done to you, rather than something you participate in and reap benefits from. The sense of being removed from the purpose and outcome of research can lead to suspicion therefore you need to be explicit about potential benefits.

*'...another question that usually sort of comes up is maybe a lot of people, the community members don't understand at the end of the day how a vaccine trial is going to benefit them, you know, they are used to probably someone coming and having a development programme in their area where they can all develop within, where they can all participate in, you know, and see results within a few months, but this is a trial that going to take say three years, like for example the malaria vaccine trial, and after that it will take much longer for them to actually determine whether the vaccine was successful, you know, etc, etc, so you know, a lot of them have this mentality sort of that we are actually just helping these people do their work, you know, so they don't have that, actually that is one of the*

*problems that I saw when I first came in into this place. People are involved in our work, but they don't get how, you know, so it's like this 'so what' question, you know, I am involved in this study. So you come to, even our other activities for example, DSS where you come into my house and ask me questions, 'so what', you know. So we've been trying to sort of tell people that once, when you are going to talk to the community, make sure you mention how it is going to benefit them at the end of the day. It may look a bit far off but make sure you do, you know tell them that you are going be part of this great thing that is going to get this, might get this vaccine that will help millions of children, you know, things like that. So we sort of try and answer that question that way, but at the end of the day, you know, there is always that question lingering [so what?] yeah, so what?'*

*CT Member, RS 06*

The latter part of this quotation expresses the CO's commitment to communicating the human angle of science. She argued that in order to capture public interest one must show how scientific knowledge will benefit both the individuals involved and society in general. Hence in addition to making science understandable it was vital in her view to demonstrate how research can help improve people's lives.

*'I am making like for example, a brochure just needs maybe four sentences about the particular trial, and maybe a magazine would need like a full page or two pages. I come and work on it and I try as much as possible to relate it to the human angle, because if someone doesn't understand how they are benefitting from the knowledge of this particular study, then, they would not take much interest in it. So I know sometimes scientists would you know be really, you know, sort of strong on the science part but so I try to humanize it.'*

*CT Member, RS 06*

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## **Review of a Community Newsletter**

In order to explore how the CT put into practice its commitment to making the benefits of research more explicit I reviewed an issue of a publication which is distributed quarterly at community level (Appendix II, Doc. 4). The publication is called the 'Dound Oganda' which means the 'Voice of the People', and it is referred to as 'A Newsletter for the KEMRI/CDC

Community'. The use of the term 'the KEMRI/CDC Community' is noteworthy in view of previous interpretations of community, cited earlier in this chapter, which tended to draw a line between the community wherein research takes place and the researchers who conduct it.

The issue that I reviewed contains four short articles which appear both in Dholuo and English. Whilst my critique concentrates on the article about the RVT it is important to note that every article in this newsletter contains an explicit or implicit reference to benefits: teenage girls receive free sanitary towels as part of KEMRI/CDC's community social responsibility programme; pregnant women are offered hope in efforts to prevent malaria; and a long-serving Kenyan employee uses training he has received from CDC to make a difference in his home area. The discourse is purposeful and communicates a clear underlying message about KEMRI/CDC's positive contributions to the communities in which it conducts research.

The article about the results of the RVT also focuses attention on what KEMRI/CDC has achieved, but with less emphasis on local benefits. The main message is that this '*incredible trial*' has shown that the rotavirus vaccine could help to save the lives of thousands of children in Africa. Public support for this trial is demonstrated by the high turnout of participants ('*hundreds of mothers and children*') and community leaders at dissemination events. The fact that community leaders voiced concerns about the distribution of benefits at these events is not mentioned; nor does the article contain any vote of thanks to the participants and the local community. The article also assumes quite a high level of understanding of technical terms such as placebo, although it does explain what rotavirus is and how it can affect children.

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This issue of the 'Dound Oganda' is an example of how publications are used to present the work of KEMRI/CDC in a positive light. The choice of name is interesting since clearly the newsletter is not written by community members but by Kenyan staff working for

KEMRI/CDC. The use of colour photos and glossy paper communicates implicit messages about the status and wealth of the organisation. So whilst the publication succeeds at making benefits explicit by the use of stories to which local people can relate, it also draws attention to differentials in access to resources. Some stories can leave readers with questions about the distribution of benefits e.g. whether a long serving employee should have had the opportunity to attend a longer training course.

#### **Level 4:**

##### **Trial Investigators:           *'Control and critical awareness'***

Trial investigators are involved in making strategic decisions about how to approach CE in individual trials. To quote a senior American investigator, *'we came up together with ideas of how to involve, how to reach these people, what are the routes, and what are we going to say'* (RS 13). Investigators described CE as a process of making sure that people have accurate information about a study, having staff out there to address questions immediately, meeting recruitment goals and encouraging community involvement. An American trial manager expanded on this by stating that CE was *'an attempt to give as much information about who you are, what you are there for, and the implications of what you are doing'* (RS, 03). From his perspective communicating who you are is important in establishing trust and ensuring that participants understand that *'we are working on their behalf, more than on the behalf of the manufacturer'*. This investigator who had lived in Kenya for over 5 years described CE as *'morally the right thing to do in an environment where education levels are low'*, and he placed particular value on forums which encourage critical thinking.

*'And being able to address a broader group of people where questions are generated that the subjects themselves may not think of brings some added benefit to the client, or possible client. Especially in this environment where education levels vary so much, sometimes you need have some level of education to ask an educated question.'*

*Male American Trial Manager, RS 03*

Interestingly there were subtle differences in the CE approach adopted by the MVT and RVT.

This was particularly evident in relation to the involvement of VRs. The RVT used VRs to help them spread the word about the study, provide feedback on community perceptions and remind participants about their appointments. The MVT team members however were not convinced that VRs should play a pro-active role in telling community members about the study. Unlike the RVT team they chose instead to use a leaflet to help disseminate information. Moreover the investigators doubted whether VRs even had the capacity to explain fully the content of this brochure. So they employed more FWs from the local area to help identify participants, sit with them and explain the process. The VRs were informed about the MVT as part of their regular meetings but they were not given extra training or delegated specific duties. This resulted in disaffection and raised questions about whether some VRs were misrepresenting the MVT at community level. For the trial manager this scenario highlighted the importance of the need to tread carefully with the community and the VRs when it comes to research.

In terms of capturing and forming public opinion a senior MVT team member expressed concerns about the capacity of the CAB which had been established by the RVT. He was doubtful about how well it represented or infiltrated the community and called for a more strategic involvement of other leaders who could influence public opinion, such as church ministers and teachers. His reasoning is explicit in the following quotation.

*'All we need from them is to understand what we do, because people go to them to seek information and as long as they do not understand what we do, then, they may not give the right information and when the wrong information is out there, it influences a lot of communities' perceptions and even attitudes towards our work.'*

*Male Kenyan Trial Investigator, RS 04*

Questions relating to the accuracy, flow and use of information are of particular significance in this context. Researchers' attempts to control the exchange of information are evident in carefully edited and pre-scripted messages, in their choice of collaborators and in their reluctance to use certain forums as means of reaching potential participants. The following social situation illustrates the latter in particular.

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## Plans for a Launch

With the active support of the trial sponsors' community liaison staff, the MVT and other senior staff had started to organise a launch to coincide with the start of the MVT. Its main aim was to reach the community where the trial was going to take place, provide information about malaria and explain the purpose of the vaccine trial. A senior scientist (RS 13) was keen to encourage an informal ambience with activities for children, quizzes for adults and short presentations about key messages. She was keen to invite a broad cross-section of the community and recognised the importance of involving community leaders. Where she became reluctant was when she heard about plans to give local politicians the opportunity to speak at this event. She was worried about what they would say and how the community would react: *'I don't know how the community will respond but I don't want them to feel like I am going to be in this because my MP told me to be in this, when and I don't know what the MP is going to say...'* She sought to argue against the involvement of politicians but Kenyan members of the organising team explained that *'once you put up a bouncy castle and a quiz show and then people will come, when people come and the MP isn't invited, they say it's like having a dinner party in your own home but you weren't invited'*. So they tried to think about how they could prevent this event from descending into a political forum. The suggestion was made to invite a senior representative from the national governmental division of malaria control to chair the launch. The idea was that he could guide other speakers on the content of their presentations or even just formally introduce *'the mayor and this person, this person, this person so they don't have to get up and say anything'*. In the end, after several meetings and quite a lot of deliberation, plans for the launch were shelved and other more traditional and less potentially problematic forums were used instead to inform people about the start of the trial.

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The 'Launch' social situation illustrates clearly researchers' hesitancy about CE-related situations that they feel unable to control or manage. In this example there was a real fear about what the politicians would say and how community members might have responded.

Whilst this is perhaps a more extreme example in reticence it serves to highlight some very important questions about impartiality. These questions also apply when it comes to the involvement of other community leaders and intermediaries. The benefits of involvement have to be weighed against the possibility that CAB members and other leaders could become co-opted and use their positions to influence others unduly. Investigators expressed concerns about this possible misuse of authority (although in other places they also stressed the importance of gaining community acceptance for research).

*'I want people to know about the study and choose the study because they want be in the study, and I am very concerned about having anything, where it is as though someone who is a figure of authority is saying, be in the study.'*

*Female American Trial Investigator, RS 13*

This suggests that among the main challenges facing those who make decisions about the application of CE are how best to manage, balance and resolve intrinsic tensions that arise, particularly relating to encouraging critical awareness, maintaining control, and reaching recruitment targets.

## **Level 5:**

### **Fieldworkers: *'We are part of this community'***

Those responsible for data collection in the field stressed the importance of *'attachment'* in community relations, and described their role as trying to bridge the gap between researchers and community. FWs from the local area described how they used their position as *'people of the community'* to complement and strengthen CE efforts. Those from other parts of Kenya in contrast had to demonstrate an affinity with the local community in order to gain trust and be heard.

*'We went out, and like sensitization, as much as the community liaison officer was going around, but we were taking ourselves as now the people of the community, now talking about the same, but not by convincing them, just information [ok].'*

*Male Fieldworker, RS 10*

*'I think it is, it, it, it resonates with the people because most people want to feel that they are part of you or you are one of them, you know, especially in this country you know when you go in and try and emphasize that you know I am not a stranger, this is who I am, this where I come from, I am part of you, you know, they tend to want to identify with you, so the more the people identify with you the better, the easier you will find it to communicate'*

*Male Fieldworker, RS 02*

In the second quotation above the field supervisor stresses the importance of persuading the local community that you are not a stranger but one of them. According to local staff it is especially important to establish one's family credentials before one visits community members' homes or speaks at public forums. The more easily people can identify with you the less likely it is that they will view you with suspicion.

*'..and most of us also come from that community so you talk of the son of whom is the one who is coming you see [so they knew you or they knew your family?] yeah, so they say if the son of whatever and he is always a good man then this is a good thing [ok] he is not a stranger, but when you come with strangers to talk to the community they feel like there is something fishy, yeah.'*

*Male Fieldworker, RS 10*

Strangers were defined as those who could not demonstrate any 'attachment' to the local community, either by birth, residency, having attended school in the area, or by having an interest in and an understanding of the area. 'Attachment' was also measured in terms of how people approached the community, whether they were courteous and respectful and whether they worked closely with local people. This notion of 'attachment' is very important in relation to CE and KEMRI/CDC activities because of the prevalent tendency to view research as something foreign. The following quotation illustrates the significance of 'attachment' in a very poignant manner.

*'Ok, there are some lines that we try to bridge [uhum] that is what I would say because, actually like when we went in part of the reason why most of these rumours came up it was because the community as Karemo, as Karemo community was now suspicious of us, as the CDC people going into them to research with them, so because of that, there tends to be that line now between them as a community and us as researchers. But it's our work as researchers going there to try and bridge that you know and persuade them that we have not come here for your harm, we have come here for, for, for your good. There is nothing*



*dangerous about us we are part of you, we are part of this community, you know, and um there is a concept we always have to emphasize when we go out that we are not strangers even when I go to barazas, you know, I try to tell them that, you know, I am working for CDC yes, but that I am a Kenyan. And even when I go down to Siaya, I am your neighbour from Kisii, you know, across, so I am one of you and I wouldn't come here to harm you, even if I am working for CDC but I wouldn't agree to certain things that would harm you because I belong to you know, I am part of you.'*

*Male Fieldworker, RS 02*

Clearly the ability to demonstrate attachment plays a vital and central role in facilitating research and overcoming barriers. By definition however attachment results in certain obligations which have to be negotiated. Most often this responsibility falls on the shoulders of FWs who build up close relationships with the families they visit over the course of a vaccine trial. They find themselves having to address expectations and explain KEMRI/CDC policies, which are not always well defined. Let us consider the example of a FW who accompanied a clinical officer to the home of a deceased trial participant in order to conduct a verbal autopsy.

*'I went there and the people came, the father was there and the mother and everybody else. So I was introduced to other people, these are, he is from CDC, from CDC, they are the people who took our baby, who were taking care of our baby. So it came out nicely that we had, we were taking care of the baby, and so I told them, yeah, we were taking care of the baby, the baby's health. And now because we had the baby and the baby had died we need to know exactly what happened, because there is a report we had to do and all that. And you see after that I was asked, so now what do you do? There are expenses we have had, what is the project doing with the expenses we have had when organizing for the burial arrangements, is there anything you can do? I had to tell them we really don't do much unless the baby died at the facility then we could do that [pay the bills at the health facility?] yes at the facility but not at home. See they don't understand they feel that is quite inhuman, it's quite unlike our culture you just walk into our compound and all you want is information, and you walk away the baby had died, a real challenge.'*

*Male Fieldworker, RS 08*

The FW felt very uncomfortable about this scenario. Culturally and socially he empathised with the family but he also had to follow standard operating procedures. In such situations

FWs frequently find themselves reaching into their own pockets since '*...our Luo tribe take it that if you go and somebody is having some problem, whatever you have just leave it there, a gift.*' (RS, 10) This sense of obligation can be contrary to research regulations and operating procedures but FWs' personal attachment to the local community compels them to respond.

*'Yeah we are not supposed in fact it is out of our protocol but you are also a human being (laughter). You are not supposed to do it, but it forces you. You get children they have not eaten from the other day and the mother went to the hospital and didn't come back. She didn't tell anybody that she was admitted they just got it that somebody told them that their mother is in Siaya. They don't have anything, you go there to get something, you leave them like that? No, you cannot.'*

*Male Fieldworker, RS 10*

FWs tend to view these types of contributions as a community responsibility that they assume and therefore they usually do not report this to their supervisors. Supervisors and clinical investigators are however aware of these difficulties and indeed encounter similar challenges in their own work. Frequently they find themselves assuming responsibilities beyond those stipulated in research protocols. For example, they go out of their way to provide nutritional supplementation for undernourished participants, and proactively follow up participants who have defaulted from HIV care and treatment services. Close engagement with communities and participants' families in this context requires all involved to negotiate boundaries of practice in a manner compatible with their personal moral codes and with reference to cultural norms and practices.

## **Discussion of the Main Themes**

The character of the KEMRI/CDC collaboration and power dynamics as between representatives from the two organizations, and within the two organizations, influence the public perception of the research programme and relationships with external partners. Promoting a positive image, giving careful attention to the content of information shared with the media and general public, and demonstrating 'attachment' to the local community are core features of the CE approach at KEMRI/CDC. A marketing logic pervades the

practice of CE and much emphasis is placed upon drawing attention to the benefits of research and seeking to appear close to the community.

It is evident that all levels of personnel have to grapple with and resolve, insofar as they can, certain tensions in the practice of CE. There is the tension of approaching partnership with a specific agenda which can result in unequal relations and restrict lines of accountability. Lines of accountability are also at the heart of tensions that exist between the desire to encourage critical awareness about research amongst members of the general public and the need to achieve recruitment targets and meet sponsors' demands. Researchers are keen to control the dissemination of accurate information about trials and are concerned about the need to minimise any undue influence of potential participants by community leaders.

Before summing up, I would like to revisit the point relating to concerns about the 'face of the research' and the way in which the KEMRI/CDC collaboration is represented and understood at community level. This point is closely related to observations about the role of 'attachment' in the conduct of an international research programme. In chapter 4 we learnt that community members typically view research as 'foreign'. This perception can be reinforced by the presence of international staff and by national field staff who place more emphasis on CDC than KEMRI/CDC. On the other hand both community leaders and community members highly value official and personal interaction with international researchers. It is evident then that the extension of courtesy on behalf of expatriate researchers and 'being known' by community leaders both facilitate the smooth running of international research programmes.

In chapter 4 we learnt how KEMRI/CDC rapidly grew into a global enterprise; here we have seen how this has resulted in the organisation and practice of science being set apart from the local community. This has propelled the need to engage, involve and reach as many people as possible in order to address any sentiments of disconnection. Researchers have also worked carefully at trying to demonstrate 'attachment' both by the employment of local staff and by creating inroads with community intermediaries. They have used these

connections in order to promote identification, trust, acceptance, understanding and communication. It is also important to highlight that disconnection and close engagement can coexist; so whilst the exercise of science is on one level demarcated from common experience it also reaches closely into people's lives. Community members develop close relationships with KEMRI/CDC personnel, and parents refer to their children as '*being with CDC*'. In a context characterised by socio-economic constraints this 'attachment' implies responsibility and raises expectations for material assistance which researchers have to negotiate in the practice of CE.

## Chapter 7:

# Village Reporters' Perspectives on Community Engagement

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*'CDC/KEMRI, they network with the community through VRs, because we get the information from them, and then we bring to the villagers, and we get them information from the villagers to them. So we are the bridge between CDC and community because what they say in the community, we take to them and then what they want to do with the community, it is us to take it to the community.'*

**Female VR, CR 39**

## Introduction

In this chapter I present VRs' perspectives on community engagement (CE). First I describe who these people are, how they are selected and outline their official roles and remit. Then I explore how these relate to and compare with their personal experiences and the challenges they face in their work. Two groups of people act as intermediaries between KEMRI/CDC and the communities in which research takes place: VRs, and CAB members. In some respects both groups share a similar brief. However their status in terms of remuneration and who they are accountable to in carrying out their duties differs. VRs are a hybrid since they are not in the strictest sense volunteers, but nor are they 'contracted KEMRI/CDC employees'. They are casual staff who represent their villages, submit reports to KEMRI/CDC supervisors and receive payments for delegated tasks and meeting attendance. CAB members' brief is to foster partnership between the KEMRI/CDC research team and the local communities. They receive sitting allowances for meetings but are not answerable to KEMRI/CDC line managers in the same manner as VRs. It is also important to note that VRs have a longer history of involvement at KEMRI/CDC than CAB members who are part of more recent developments in the evolving way in which the organisation relates to the community.

This chapter focuses on the perspectives of VRs and draws on empirical data from a series of interviews and a group discussion with 9 VRs. These interviews took place between May and October 2009 at a time when the RVT was coming to an end and the MVT starting up. VRs

were invited to take part in an interview during a meeting held for all VRs. One of the demographic surveillance team members introduced me to a representative group of VRs drawn from all the areas where the vaccine trials were operating. With the support of my research assistants I explained the purpose of my study to this group of VRs and asked whether they would be willing to participate in a series of interviews and whether I could join them on some of their home visits. All of the VRs we spoke to agreed to participate and we made appointments to visit them in their villages. This chapter is informed by the interviews held with this group of 6 female and 3 male VRs. It is also informed by observations made during household visits with these VRs and regular meetings between KEMRI/CDC personnel and groups of VRs. I also reviewed pertinent conversations and interviews with researchers and consulted secondary sources such as KEMRI/CDC figures and standard operating procedures relating to VRs.

At this juncture I include a brief review of relevant literature which informed my analytical thinking for this chapter and the following chapter which discusses CAB members' perspectives on CE. Some of this literature has been cited in chapter 1 however here I look at it with a particular focus on questions of relational ethics.

## **Review of Relevant Literature**

Community involvement in promoting and sustaining health was championed in the Declaration of Alma Ata on Primary Health Care (World Health Organisation, 1978). This Declaration stated: *'the people have the right and duty to participate individually and collectively in the planning and implementation of their health-care'*. Community participation and self-reliance were stressed as being invaluable to achieving sustainable development. The Alma Ata recommendations were widely adopted in developing countries by policymakers, health professionals, funders and communities, and implemented to differing degrees with varying success (Oyaya and Rifkin, 2003, Rohde et al., 1993).

The involvement of community members under various names such as 'village health helpers' or 'community health workers' was integral to Alma Ata and subsequent initiatives in developing countries prioritised the training and equipping of health volunteers. Despite a move away from community-led health programmes during the late 1980s there is now a

renewed focus on the involvement of such volunteers. The Kenyan MOH, for example, launched a strategy for the delivery of essential health services to the community in 2006 which is premised on the involvement of community owned resource people (Ministry of Health, 2006).

### ***Community engagement and collaboration at community level***

Community-based volunteers also play a significant role in health research in developing countries, where they act as intermediaries between lay people and scientists. The involvement of community intermediaries reflects the increased attention paid to CE as means of protecting communities (Benatar and Singer, 2000, Benatar and Singer, 2010, Emanuel et al., 2004). In a framework developed by Emmanuel et al. (2004), collaborative partnerships between researchers, health policymakers and the community are conceived as being a way of ensuring that research is ethical. In practice, CE is defined as '*a process of working collaboratively with relevant partners, who share common goals and interests*' (Tindana et al., 2007).

### ***An ethics based on relationships, attachment and familiarity***

Respectful relationships are core to the Emanuel et al. (2004) framework and their detailed reference to benchmarks for measuring good practice has initiated broader discussion about ethics and community. Overreliance on formal guidance, principles and a related 'tick box' mentality can stifle ethical reflection. Accordingly, Geissler et al. (2008) argue that '*research ethics should make space to unfold ethical relations*'; relations which either pre-exist or which develop in the implementation of public health trials. Drawing on ethnographic research into interactions between FWs and villages hosting vaccine research, they highlight the importance of attachment and familiarity versus detachment. Whilst attachment made it difficult for FWs to uphold certain trial restrictions (e.g. medication being available only to trial participants), the formation of social bonds allowed FWs' interactions to be guided by their '*ethical impulse*' or moral compass. Geissler et al. (2008) argue that in order to achieve a correct balance, ethical guidance should be complemented by considerations arising out of interactions characterised by trust.

### *Trust, the social context and the role of CIs*

Trust is a relational notion which describes a voluntary relationship between two or more people (inter-personal trust) or between a person and an institution (institutional trust) (Gilson, 2003). Molyneux and colleagues demonstrate its importance with particular reference to consent and community perceptions of research (Molyneux et al., 2005a, Molyneux et al., 2005b). Their work emphasises the need to understand the social context and ensure that research teams incorporate both technical and inter-personal competence. The latter may be achieved by employing community-based assistants who are known and trusted by local residents (Gikonyo et al., 2008). In international public health research such employees are often referred to as FWs. Their wide-ranging duties mainly relate to data collection, recruitment and consenting participants. FWs are usually secondary school leavers seeking opportunities to develop skills and obtain training and work experience. They are employed on renewable contracts and serve as cultural brokers for researchers who do not come from the trial area.

FWs are not the only type of community intermediary common in the implementation of international health research. As noted above, community or village health workers play a role, as do 'peer recruiters' and more advisory interlocutors such as CAB members. Whilst the advantages of CIs are evident some attention has been drawn to ethical considerations. Simon & Mosavel's (2010) concern is the potential for '*vertical exploitation*' of CIs. They argue that this occurs when outside researchers exploit community intermediaries social connections with local community members to promote research. Specific reference is made to recruitment practices, but '*vertical exploitation*' also covers potentially unfair employment practices. '*Horizontal exploitation*', by contrast, is described as occurring when community intermediaries exploit their partnerships with outside researchers to gain power and influence within their communities (Landy and Sharp, 2010). These dual ethical concerns demonstrate that power relations have to be taken seriously and thought about carefully in the conduct of research and related CE.

In this chapter I explore the experiences of VRs who support research conducted by the Kenya Medical Research Institute in collaboration with KEMRI/CDC. VRs' perspectives are of



interest since they reside permanently in the villages in which they work, and so must balance kinship, cultural and professional boundaries. Unlike FWs, they are casual workers and not contracted employees; consequently they are not so closely accountable to researchers. VRs are comparable to other casual employees engaged as CIs in similar settings in the developing world. This provides additional justification for documenting their experiences and considering their practical, ethical and theoretical implications.

## **Institutional Framing of the Role of Village Reporters at KEMRI/CDC**

*'...we also have a system, a VR system, they are very resourceful, we use them to capture the feelings at the community, at every village level.'*

CLO, CR 01

Since KEMRI's establishment in 1979, and inspired by contemporary ideals of Alma Ata, village volunteers have played a vital role in its activities. In the Saradidi Community Health and Development Programme 'village health helpers' acted as agents of change to promote health development through community-initiated projects (Kaseje and Sempebwa, 1989). However, as KEMRI's portfolio expanded, trials began to be conducted separately from community-led projects. In collaboration with CDC, KEMRI developed extensive research infrastructures in western Kenya. This collaboration is formally referred to as the KEMRI/CDC Research and Public Health Collaboration and it accounts for a substantial part of the KEMRI research programme. In the areas where we conducted our field work community members often referred to this collaboration simply as 'CDC'.

With the expansion of the research programme a clear demarcation became apparent between the practice and social organisation of science, and regular health services and community activities. Alongside this, the role of village volunteers within KEMRI/CDC evolved from being agents of change to becoming community intermediaries and facilitators of research. Their involvement was formalised with the establishment of a health and demographic surveillance system (HDSS) in 2001. They became referred to as 'VRs', and standard operating procedures (SOPs) were developed by KEMRI/CDC to define their role.

According to one of these SOPs (Text Box 2), VRs represent the *'interface'* between the community and KEMRI/CDC staff. Hence the nature of their work is bi-directional and challenges can arise in their interactions with community members and researchers. The term *'interface'* takes for granted that there is a gap between the practice of science and community experience. VRs are seen as those who can cross this boundary and create inroads which will facilitate research implementation. They can also provide insights about the nature of this boundary and its implications for practice.

**Text Box 2: Definition of Village Reporter**

*'A Village Reporter (VR) is an individual selected by the community members after meeting specified criteria, to support the implementation of KEMRI/CDC projects and studies. This individual is the interface between the community and the KEMRI/CDC staff. The VR will support all KEMRI/CDC projects in the designated geographic area. The support offered by VRs is an essential and valued component to the success of our work. The village reporters are not permanent employees. They are engaged by projects on a need basis and are paid centrally according to how many days/hours they work.'*

*Standard Operating Procedure No 11, version 1<sup>st</sup> November 2011*

In this SOP VRs' duties are described as falling broadly into three areas: 1) capturing data on births and deaths for the HDSS; 2) mobilising the community; and 3) serving as a community resource. VRs primary responsibility is the notification of births and deaths at weekly zonal meetings with HDSS supervisors. However they also play an important role in mobilising the community which includes raising awareness about the work of KEMRI/CDC and providing researchers with feedback on community concerns, misconceptions or rumours. Some projects also train VRs to support trial-specific education efforts at village and household levels. VRs are viewed as a resource both for the community and for researchers; they are encouraged to participate in health education activities and researchers rely on them to facilitate community entry. In addition to these core duties some trials have trained VRs to assist with technical responsibilities such as reading Tuberculosis skin tests.

People interested in becoming VRs are nominated by their villages according to criteria provided by KEMRI/CDC. Their selection is endorsed by village elders and administrative chiefs, *'because it is now again upon us to identify good people for the CDC to be VRs'* (Assistant Chief, 56). VRs' main responsibilities are to record births and deaths for the HDSS

and provide this data at weekly meetings. Trials also involve VRs in mobilisation, identifying and following up participants. VRs are primarily accountable to the senior KEMRI/CDC community liaison officer, but they also report to HDSS field supervisors, trial supervisors and trial-specific community liaison staff. Formalisation of the role of VRs in 2001 led to changes in the range and type of people engaged. Earlier trials mainly involved nyamreche (traditional birth attendants) who were typically older women who had benefitted from additional training from governmental and non-governmental organisations. The new selection procedures resulted in a broader representation across age, and to a certain extent, gender.

Currently there are 414 VRs working in the health and demographic surveillance area; 171 (131 women, 40 men) of these are based in the area where this study was conducted. In Siaya town, the urban centre in Karemo, some VRs represent designated areas where they either live or where they can establish contacts. VRs receive regular payments for allocated duties which are administered by financial officers within the human resources department at KEMRI/CDC. They receive Ksh70<sup>5</sup> for the notification of a birth or a death and Ksh 300 for attending weekly meetings. For other activities they are paid an hourly rate of Ksh 40 if they work less than 4 hours per day and a daily rate of Ksh 320 if they work longer. Project leaders have to sign VR's time cards which the VRs submit to the community liaison officer (CLO) by the 20<sup>th</sup> of each month in order to receive their payments by the end of each month. These payments are transferred into a bank account which KEMRI/CDC recently opened for each VR. I was given access to payment information for VRs based in Karemo for January, February and March 2011 which suggests that on average VRs earn approximately 2100 Ksh (US \$ 28 ) a month. The most one VR claimed for one time period was Ksh 7450 (US \$ 99) and the least Ksh 1570 (US \$ 21). This is comparable with information given to one of my research assistant by a few of the VRs we interviewed. They stated that the minimum a VR can earn per month is approximately Ksh 1400 (4x 300) plus some additional payments for demographic reports) and the maximum Ksh 4000 (4x 300) plus payments for reports and other duties). The average monthly income was estimated at about Ksh 2500 (US \$ 33). For the VR who makes approximately Ksh 4000 a month this is a substantial addition to the Ksh 2000 he can earn from farming his land and selling milk.

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<sup>5</sup> At the time of my fieldwork the US \$/Ksh conversion rate was 75 Ksh to US \$ 1.

This helps to explain why these types of semi-voluntary positions with fixed payment rates are very sought after in communities where there are limited formal employment opportunities. VRs conduct their duties alongside other activities; many volunteer for other organisations and most are small-scale farmers. They belong to a growing social group who seek out as many informal employment positions as possible to make a living and support their families. Their average income is equivalent to that of a labourer or watchman working full time in the city of Kisumu and represents a substantial addition to their other earnings – in particular as it does not involve relocation.

In addition to VRs monthly payments a special one-off allowance of Ksh 2000 (US \$ 27) is given to the families of VRs who die to help them buy a coffin (the cost of a coffin at the time I conducted my fieldwork ranged from Ksh 5000-20000 (US \$ 67-267) according to one of my local research assistants). The history of this allowance can be traced back to the time when the insecticide-treated bed nets trial was coming to an end and the HDSS was being set up. The prevalence of HIV in the demographic surveillance area and limited treatment options contributed to an increase in deaths amongst KEMRI/CDC personnel and VRs at that time. In solidarity KEMRI/CDC personnel - including international researchers - paid something out of their own pockets to help the families of the deceased. Funerals are significant occasions for the Luo and it is a cultural norm for kin, friends and patrons to contribute funds towards funeral costs and family welfare by means of an organised 'harambee' (let's pull together) collection prior to the event or an informal whip-round (hat) at the funeral. This informal expression of solidarity and the close connections between field staff and senior researchers led to a sense of obligation to formalise a set allowance for the families of deceased VRs. Today this allowance is viewed as somewhat anomalous both by KEMRI/CDC staff and some VRs who would prefer to receive other support to meet current medical expenses. However it is important to recall that this allowance was authorized at a time when there was limited access to antiretroviral therapy, a significant consideration given the heightened prevalence of HIV in the areas where VRs reside.

## Village Reporters' Perspectives

In this section I synthesize VRs' perspectives on their role and the challenges and opportunities they encounter in their work. At the outset it is important to state that in contrast to VRs working in some of the original places of KEMRI/CDC activity the VRs I observed and spoke to are relatively new to KEMRI/CDC. They became involved in the KEMRI/CDC research programme in 2006/7 when the HDSS system was extended to Karemo division. The programme in Karemo has however grown significantly since 2006 and most of the VRs based in this division have supported a wide range of activities, observational studies, malaria surveillance, HIV home-based care and testing and vaccine trials. We must also remember that VRs live in impoverished areas and they are keen to secure work to support their families. They are employed as casual labourers and their position can be viewed as vulnerable. Even so, while they all spoke openly about challenges they face in their work they also stressed its' positive aspects.

VRs include a wide range of people, from those who are young and ambitious, to mothers with young children, middle-aged and older community members. Amongst the younger contingent, personal circumstances have usually meant that they were not able to pursue further education and better employment opportunities. In general VRs' association with KEMRI/CDC affords them recognition, a regular income and some opportunity for self-development, which I will comment on in more detail below. At the same time they confront limitations due to their lack of formal qualifications, the casual nature of their employment, trial requirements and researchers' perceptions of their capacity. VRs are particularly sensitive to the value placed on their role by individual trials. They gauge this from the level of interaction between themselves and members of the project team, the training received and the level of responsibility and nature of tasks assigned to them. In the following five sections I explore their perspectives on becoming a VR, their role, the nature of their work, their view of CE and the challenges they face in being a VR.

## **Becoming a Village Reporter**

*'We were like five people and people queued behind us, that is the way we were elected, not nominated really, but elected by the community.'*

*Male VR, CR 32*

The announcement that KEMRI/CDC wanted each village in Karemo Division to select a person who could serve as a 'go between' was made at chiefs' barazas in 2006, a few months before the HDSS started conducting surveillance activities in this area. The response to the announcement was very positive and in some instances the selection process took place during the same baraza. The chiefs had alerted community members that something important was going to be discussed and hence attendance at these particular meetings was high. Members of different villages asked to go aside in groups in order to reach consensus about who should represent their village. In other instances chiefs called for elections to take place at village level and in some cases this led to very heated campaigns.

*'We call the elections in each and every village [ok, right,] and the election was very hot [mmm] you know they believe they will be paid [right], like the other place we had to repeat it twice [right] mmm. Sometimes we used to call the community liaison officer and the team to oversee the elections [right, because] because there was a campaign like, just like a MP (Member of Parliament).'*

*Chief & CAB Member, CR 25*

As the above quotation indicates chiefs and KEMRI/CDC personnel played an integral role in the selection of VRs. Chiefs were keen that 'good people' be identified and were not so concerned about selection criteria while members of the HDSS needed to make sure that elected VRs had the capacity to complete designated duties. The latter was established during short interviews and a seminar held to teach potential VRs about the HDSS and their potential role and responsibilities. Despite this official involvement in their selection all of the VRs to whom I spoke were very keen to stress that they had been elected by members of their villages.

*'There were some jobs that we were supposed to do in the village and therefore, the village elder was not supposed to choose his person. It is the villagers who knew whoever can work for them very well.'*

*Female VR, CR 39*

When I asked interviewees why they had been interested in becoming a VR they cited several key reasons. These included the possibility of financial remuneration, the opportunity for self-improvement (e.g. to learn more about health) and the desire to make a difference at community level. Election earns VRs significant respect at community level, and improves their status both financially and socially. VRs understood that KEMRI/CDC had come to help improve health conditions and many of them had either worked as community health workers already or been involved in health education as members of drama groups. Out of the 6 women I interviewed all were mothers and most were married, two had trained as community health workers with non-governmental health organisations and one of these was a traditional birth attendant. The youngest of the women was very active in her community and also worked as an assistant at her local chief's office. She expressed ambitions of becoming a chief or gaining political standing. Out of the three men, two were young married men with young children and the other was retired. The younger men were very active and vocal members of their respective VR groups. One in particular was keen to draw attention to VRs working conditions and the need to raise their payments and increase their allowances.

*'Yeah, at first, I was interested in employment because I was just working like a peasant farmer...and when I heard about how they used to pay people, I decided that I should go, and secondly, I wanted to do something for my community that can create impact [mmm], mainly on health issues and [mmm] social related issues [ok].'*

*Male VR, CR 32*

*'I was much interested to be one of them, yeah. I thought that they could make somebody know more about health of the people around, and I knew that they are dealing with health. They want to control the diseases that are disturbing the people around.'*

*Female VR, CR 27*

Before becoming VRs my interviewees had only a limited understanding of the nature of KEMRI/CDC's work and tended to associate it with the prevention of malaria and distribution of bed nets. A couple of them knew that KEMRI was the research arm of the Ministry of Health (MOH) but the others were less aware of the research angle of the KEMRI/CDC programme. What they had heard at or via barazas and seen in adverts posted at chiefs' camps is that KEMRI/CDC was offering a range of employment opportunities. Some even applied to become FWs however they were not successful due to a lack of schooling or low grades. This did not put them off and since they were keen to be part of KEMRI/CDC they expressed an interest in becoming VRs and sought to gain their villagers' support and nomination. This notion of being one of them or part of KEMRI/CDC is of interest and something we will continue to explore it through the course of this chapter and the thesis.

### **Village Reporters' Role**

*I work as a mouthpiece of CDC in my village and a mouthpiece of my village to CDC, [so you see in both ways] yah, I speak to my village, I speak for my village and I speak for CDC [ok] yeah.*

*Male VR, CR 32*

VRs describe themselves as the 'baseline' (which is an interesting use of a research term), those who collect data and form a vital link between KEMRI/CDC and the local community. The above quotation suggests that they understand their role as being a spokesperson both for their village and for KEMRI/CDC. In practice this involves an exchange which prioritises explaining the purpose of research and addressing related community concerns. As part of this process VRs are required to account for the work of KEMRI/CDC and can be called upon to act as arbiters. The term 'your people' in the following quotation underlines the strength of the association of VRs with KEMRI/CDC.

*'You may see sometimes that a fieldworker comes to a certain home [mmm], they refuse him and then send someone to me, that those people, your people came here and I chased them away, come and explain to me what they wanted'.*

*Male VR, CR 32*



When it comes to explaining research VRs stress the importance of making sure that villagers understand the main aims of different projects, the voluntary nature of trial participation and the potential benefits of research. They try to clarify that the purpose of health research is to prevent and address the causes of disease and they describe the benefits as being closely aligned to these aims. This helps them to counter expectations which can extend beyond the remit of research projects - e.g. when in the process of collecting mortality data they are frequently asked whether KEMRI/CDC can contribute to funeral costs. I will return to explore pick up on this challenge and expectation below.

VRs are expected to mobilise the community and share information about studies. However there is some uncertainty as to whether 'mobilisation' is the same as recruitment or whether it is just about raising awareness and encouraging people to find out more. 'Mobilisation' is a term used in formal documents (e.g. the VR SOP) and it is also used frequently by researchers in conversations or descriptions of CE activities. It is however a term, which is difficult to define in practice and is used variedly by different people and groups. In one trial taking place at the time of my field work VRs were asked to identify potential participants and take FWs to their compounds. In this instance VRs clearly played a significant and direct role in the recruitment of participants. In the RVT VRs were asked to tell mothers with newborns about the study and to advise them to go to their local health facility if they wanted to find out more. By contrast the MVT researchers were much more hesitant about involving VRs in the distribution of information about the trial and had doubts about their capacity to explain the content of a recruitment brochure. There are thus clear differences in the way in which individual trials interpret mobilisation and how they involve VRs in awareness-raising and recruitment.

VRs themselves are more definite about what mobilisation means and view encouraging people to participate in trials as an integral part of their work. They also describe how their close relationship with villagers means that they are particularly well placed to do this.

*'They take part because they know us, they know that they will get free treatment. Secondly, the child, the child will be monitored throughout the time the child is enrolled, so that is why they. Secondly they see, thirdly they see that if the person within the community, if the VR has just informed them about the research going on, they say, no this is a good thing [if they hear it from you?]. Yeah, this is a good thing not a bad thing (because they trust you or?). Yeah, they trust us and they know that the kind of work we are doing is a good work. So they say no, I have to enter.'*

*Male VR, CR 38*

In some instances VRs can be quite proactive about promoting research and may well use their own personal experience to offset rumours and underline their perception of the benefits of research participation. This is of concern especially since, whilst VRs do state that participation is voluntary, they seem not to lend much weight to the disadvantages and potential risks of taking part in vaccine or other trials.

*'I welcome all the research now, I only tell the people in my village the good that I have seen in being in the study, so I tell the villagers that if you might think that your child might be sold<sup>6</sup>, then even ours are in the study, so and so child is also in the study, so it is something that has been brought to help us but not to harm us.'*

*Female VR, CR 29*

The above quotation and observations raise questions about the impartiality of VRs and their capacity to speak on behalf of their respective villages in view of their close association with KEMRI/CDC. To further illustrate this, the following quotation describes aptly how VRs frequently find themselves in a position of having to defend the work of KEMRI/CDC, which can make it difficult for them to remain objective or to present a fully accurate and unbiased picture to their communities.

*'...these people need VR who can answer them correctly...but if you are weak they can push you towards the wall and you cannot know how to answer them (they can give you a hard time) but we don't want to tarnish the work of CDC down we want to uplift it and make it different with other organizations<sup>7</sup>.'*

*Male VR, CR 38*

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<sup>6</sup> Such concerns were raised at community level regarding the trials. I have mentioned such concerns in chapter 4 and will talk more about them in chapter 9.

<sup>7</sup> Some non-governmental organisations have a negative reputation in these communities. They are described as briefcase organisations because they come and go, are not committed to the local community and there is a lack of transparency about how funds are used.

Such 'concerns with impartiality' are my own personal reflections and relate to my interpretation of bio-ethics. They are not concerns which were raised directly by VRs themselves or other community leaders. Indeed community leaders spoke very positively about the work of VRs, noting that VRs play an invaluable role in addressing questions at household level. Most researchers also stressed that VRs are recruited because they are respected village members and the main premise of their work is to support KEMRI/CDC activities. A few however expressed hesitation about VRs competency and how VRs could use their position as a means of undue influence.

### **The Nature of their Work**

*'To some extent we are working for KEMRI/CDC as volunteers and we are serving our community, the bigger percentage is just to serve the community.'*

Male VR, CR 32

VRs described the nature of their activities as '*partly volunteering and partly working*'. This is of interest since according to official documents they are hired or engaged by projects to perform specific tasks. This would suggest that they are employed on a casual basis and are therefore not volunteers. The informal nature of their work and the inherent value attached to volunteerism in the field of health and development however leads them to describe the job they do as '*partly voluntary*'. Whilst VRs maintain that the payments they receive do not adequately reflect their efforts they are very careful to stress their willingness to work and their commitment to selflessness. VRs inhabit what Brown (2011) describes as the '*grey area that exists between voluntarism and paid labour*' and they understand that selflessness affords respectability which opens up opportunities for financial gain and self development.

Despite some dissatisfaction with their working conditions it is important to draw attention to the value that VRs place on their association with KEMRI/CDC. It has earned them respect at community level and improved their status both financially and in terms of social relations. They view their work as an income-generation opportunity which has provided them with a level of exposure which they would not otherwise have obtained. Exposure in this instance means the experience they gain and the new things they witness by being

connected to KEMRI/CDC in terms of training, public relations, meeting people and accessing resources.

*'The best thing of being a VR, the best of all being, you know, now I might say they are, even though it's a voluntary service but I see that it's not voluntary because now, at the beginning, I didn't know where the bank was, even though I knew where it was, but I happened not to have entered in [eeh], our leader, the community liaison officer, had made efforts, we are now having the ATM cards that I could have not got if it was not for the being a VR. Another thing is that I might talk to a white person like you which I might not talk to if not being a VR [mmm], another thing is that I am now known everywhere by all tribes [eeh] and I know how to interact with the people, I know how to make my PR (public relations) to be better [mmm] than, I know how to better it [mmm, ok] yeah.'*

*Female VR, CR 30*

The status that VRs gain from association with CDC is further illustrated in the following quotation from a CAB member. This interview excerpt also provides some insight as to why more emphasis is placed on CDC rather than KEMRI.

*'You see people, in fact KEMRI's name has died a natural death within the villages it is CDC that helps. Yeah, she is from CDC, you see we have the VRs [yeah], and you see, most vehicles that run around here are written CDC, and the VRs, you see eh we have very learned women, those actually they reached, they have finished their basic education, they got married, they have been staying in the village for so long, you see, the VRs most of them are women [yeah]. Then when CDC came, CDC recognized their importance, a woman who can read and write, and therefore, they were contracted to do some worthy work within their villages. So what do they do? They want people to know that they are really connected with CDC and therefore they scrap away the word KEMRI and remain with CDC, and therefore, everything is C, CDC. So anything that is happening within the village is C, CDC not even KEMRI.'*

*Female CAB Member, CR 02*

With the above-cited benefits in mind the VRs I spoke to were keen to be given more work by KEMRI/CDC. At the same time they also called for a review of their working conditions, stating that since they first started as VRs there had not been a 'salary' increment. Some of them spoke more specifically about the relationship between remuneration, motivation and the response to research at village level.

*'So first, I think when the, the CDC/KEMRI wants to change the whole thing and to affect [mmm], the village positively in a big way, [mmm] or in a good way, they need to adjust that payment for the VRs so that we may be motivated [mmm], yah, because the cost of life is going high, and when we started we were being given 290 shillings. But when you compare the price of sugar when we were starting, it was 45 a kilogram, today its 90 [mmm], such things also can maybe interfere with some little things in the research.'*

*Male VR, CR 32*

Similarly, but from a slightly different angle, another VR talked about how people were surprised that even though she is working with KEMRI/CDC she cannot pay school fees. She thought that KEMRI/CDC should take the problems that VRs face into careful consideration, especially since they rely so heavily on VRs as community intermediaries. To quote; *'without VRs, in fact you can't go through without VRs, because we are the grassroots'* (Female VR, CR 29).

These quotations also suggest that questions of pay and working conditions can rightly or wrongly have a direct knock-on effect on community members' views of research and VRs' relationships with researchers. Indeed these quotes stress VRs unique positioning and leverage and convey the need for researchers to recognize, acknowledge and appropriately reward their influence.

### **Village Reporters' View of Community Engagement**

*'...CDC goes straight to the community, and in villages and in houses.'*

*Female VR, CR 29*

According to the VRs I spoke to KEMRI/CDC engaged very closely with local communities; meeting people not only at barazas but also in their villages and homes. The VRs viewed their own role as central to the practice of CE and drew upon historical and contemporary examples to illustrate this. From a historical perspective they argued that their employment at the start of the research programme facilitated community acceptance and made people feel that *'the work that is going to be done here is part of the community'*. Even several years into the programme they differentiated clearly between the advantages of their approach in contrast to that of field workers.

*'Yeah, the approach to the community [yah], there is a little difference [mmm] yah, because some [yah], use the VRs to create the awareness or to mobilize or to tell people about the project [eh], but some come individually. They come, the projects, the staff, project staff [yah, yah], they come themselves [ok], so there is some little difference because you are a villager and you are VR [mmm], so if you take the message to them [mmm], somehow they understand it better [mmm], and feel part of it [mmm], and it is different from, if the staff, project staffs, they come by themselves.'*

*Female VR, CR 29*

In VRs' self perception, they believe that their value lies in their close attachment to the village; they are trusted and can therefore 'open the way' for others. The reasons why they are nominated to be VRs are more difficult to discern and may not always be because they are trusted. It may, for example, have more to do with respect and familial and cultural obligations. VRs may not necessarily be people in whom others would always confide in. However they do seem to enjoy a certain standing in their villages which could be due to various factors e.g. their age, marital status, assets, religious affiliation, strength of character and ability to influence others.

VRs repeatedly stressed the value of their close attachment by referring to scenarios when their absence had made villagers uncomfortable and in some cases resulted in FWs being chased from compounds. They thought that KEMRI/CDC should adopt an approach which encouraged much closer collaboration between project staff and VRs in order to overcome suspicion and encourage trial participation.

In line with sentiments expressed in the previous paragraph VRs tended to define 'community' as those living and working together in close proximity. They equated this with their village and the people who shared something in common with them, for example a school, a health facility or a water point. Some also drew attention to the importance of communication, shared goals, mutual support and positive interaction when they talked about the nature of community. This close-knit understanding of community explains in part the heavy emphasis that VRs place on their role as the pathway for KEMRI/CDC in terms of CE.

## Challenges Faced by Village Reporters

*'...when I enter a home they think I have some gift to give them they say that you have to bring us something that is the main challenge...when you enter any home they know that you carry something for them.'*

Male VR, CR 28

The main challenges encountered by VRs in the course of their work can be summarised under two broad themes: negotiating working relationships; and managing community expectations. I will consider each in turn.

As noted in chapter 5 in the recent past different KEMRI/CDC projects have chosen very varied approaches to CE, trial recruitment and participant follow-up. These have involved VRs to varying degrees and resulted in VRs comparing and giving preference to certain projects above others. By this I mean that they put extra effort into studies which involve them more than other studies do. They talked more positively about the former category of studies in conversations and interviews. This preference is partly related to remuneration but importantly it also has something to do with the value that VRs perceive to be attributed to them by particular projects.

*'Ok, the real issue is that with the KEMRI/CDC is like we have so many projects [yeah, yeah], and the way they pay their people is different [ok]. Like now you can see that the Tuberculosis project [mmm], is like is making use of so many funds like a, once you are taken to the training, you are given refreshments [oh, yah], and again the type of, the number of days that they give you [mmm], are long. Now you will find the malaria people [mmm], they take you to the training [yah], there is no refreshments that you are given [mmm], and the number of days for mobilization that you are given is less [ok], so that's why they were complaining.'*

Female VR, CR 30

When a project fails to engage VRs' services or simply expects them to undertake additional duties alongside their regular HDSS activities without additional payment, they feel sidelined and undervalued. This heightens their awareness of the unpredictability of their role and related benefits. As a result they are less inclined to support such a project which can have negative repercussions on the general community response. Whilst it is trial investigators'

prerogative to determine how they will involve VRs based on protocol requirements and related plans for CE and recruitment VRs can be active in seeking more involvement. They also try to negotiate better working conditions by putting pressure on those who supervise them most directly such as trial-specific liaison staff. However they find it more difficult to voice their complaints in person to the community liaison officer (CLO) both for fear of losing their job and the nature of his response.

Unvoiced discontent can lead to a lack of motivation which is observed by trial staff and communicated to the CLO. When this happened in the MVT the CLO called for a general meeting of all VRs working across several zones. The size of the gathering was perceived as a barrier to communication by some VRs. However a few did stand up to complain about their lack of involvement in the MVT. The CLO responded by stating that projects can use their own discretion on how and whether they want to engage the services of VRs. VRs should accept this and not work against these projects but remember that they represent the whole research programme and are paid centrally by KEMRI/CDC. When I spoke to some of the VRs after this meeting they were not completely satisfied with his response and wanted the CLO to discuss these issues in more depth with them in smaller zonal meetings.

The other main challenge that VRs face is how to manage peoples' expectations in the course of their work. To a certain extent some of the expectations the VRs encounter are the result of community members likening the KEMRI/CDC programme to that of a non-governmental organisation and comparing what they receive from it with what other non-governmental organisations provide. They do not see the point of so many questions during surveillance visits and think that they should be paid for their time or at least given a token of appreciation.

*'...but CIs when they come, they just ask questions and go, [yeah] ask questions and go. So the villagers came to me and ask me, why don't you give people things [mmm], because these, your people just come and ask so many questions and they go without giving anything [right].'*

*Male VR, CR 32*

To elaborate more poignantly on the problems which VRs can face in negotiating



expectations one VR told me a story about an occasion when he met with a group of researchers in his village. There were two 'wazungu' (a term used to denote white people) and a Kenyan and after they asked him for directions to a particular compound they invited him to accompany them on the visit. They were conducting a malaria parasitaemia survey and needed to collect some blood samples from this household which had been selected at random. The following are the VR's recollections of this visit:

*'When they arrived there was only one mama who was very old, ninety something years old and she didn't have something to eat, she didn't have something to wear, she was old desperate and poor and the same time she was sick. What they did, they just took blood, and she was staying with her grandson, so after taking blood, she was given some medicine. Was it medicine? I think some tablets. Again we went to look for her grandchild who was working, trying to train as a carpenter, next to the prison, so we brought him back, asked him some questions, also we took blood from his finger tips and we went away with those wazungu. So people were asking me, the state of that woman, could we just even just give her ten shillings or fifty shillings, and we have walked with two wazungu and someone who is senior in CDC, we just take blood from this woman, we know she anaemic, she don't have something to eat, she is desperate and poor, you just take blood and go away that you are doing research on malaria. Is it normal surely, if a muzungu (a white person) can come to a house like that, that house was pathetic, a grass thatched house that is leaking. So I had a lot of hard time after that because that woman was too old, too poor, too desperate and was living in a compound alone. That grandson used to come at night and go out at dawn, so they asked me why don't you even just give one hundred shillings to that woman for a kilo of sugar, of unga (flour).'*

*Male VR, CR 32*

In this instance the VR's close proximity to the household made the situation all the more difficult for him to deal with. He could not just get up and leave, he had to face questions from other community members. Moreover when he got home the mama was waiting for him expecting something in return. Dipping into one's own pocket to support a neighbour is a cultural norm and social expectation (Shipton, 2007). In Luo communities giving, exchange and entrustment are associated with being a 'good' person.

Faced with such situations VRs often find themselves having to defend the work of KEMRI/CDC whilst also reaching into their own pockets to respond to need. To a certain extent they view the latter as their neighbourly responsibility, particularly when it comes to cultural norms such as funeral contributions. On the other hand these kinds of scenarios

highlight the practical and ethical difficulties VRs can face in remaining sufficiently impartial whilst responding appropriately to evident need. These difficulties are compounded by the fact that there is no budget apportioned by KEMRI/CDC to deal with such scenarios and indeed it could be difficult to institute such support fairly. On the other hand the lack of such provision contradicts embedded cultural norms and obligations. It underlines the difficulties in negotiating expectations which arise as a research programme expands and crosses boundaries of relationships and obligation.

## **Discussion of the Main Themes**

VRs belong to a social group who seek out as many informal or formal employment positions as possible in order to make a living and support their families. They are careful to stress their commitment to selfless community service since it augments their respectability at community level and opens up opportunities for financial gain, exposure and self-development. They value the status they gain from association with KEMRI/CDC and are keen to work even if they view their contribution as *'partly volunteering and partly working'*.

VRs stress their unique approach and invaluable role in CE and trial implementation. How they describe these is reminiscent of concepts presented in the literature on relational ethics (Gikonyo et al., 2008, Molyneux et al., 2005a, Geissler et al., 2008). VRs value their work with KEMRI/CDC and hold the trust of many people in the places where they live and work. But, as this chapter has shown, challenges can arise from trust, attachment and relationships with researchers which must be recognised, understood, and properly addressed in order to realise the full positive potential of community intermediaries such as VRs.

VRs are referred to as a means of capturing community feeling by the CLO. In addition to undertaking set data collection tasks for researchers they are also expected to support the work of KEMRI/CDC in their villages and feed back any potential concerns about the programme to researchers. This suggests that although they are nominated by fellow villagers as village representatives, the premise of VRs' role is not about community advocacy but the facilitation of the research programme. In practice this means that VRs

have become closely aligned with KEMRI/CDC and have to balance competing allegiances. It also raises questions about the potential for misuse of trust, close relationships, and undue influence in promoting trials. However, such challenges can cut both ways. For example my findings show that low morale can affect how VRs relay information about trials within their communities. VRs who feel dissatisfied over their involvement in specific trials can be passive towards, or even influence opinion negatively against, such trials. Partly, this phenomenon stems from their remuneration system (according to work done); partly, it depends on how far VRs feel that their contribution is appropriately recognised and appreciated. This is a different form of misuse of power relations than those already described by Simon and Mosavel (2010) and Landy and Sharp (2010). VRs in this case are controlling their social networks and making it more difficult for researchers to benefit from them.

Managing villagers' expectations of concrete assistance is a further challenge related to the concept of attachment. VRs' physical, familial and cultural proximity to trial participants places them in a difficult position of having to negotiate implicit and explicit expectations of help in a cultural setting in which sharing and mutuality remain cherished - if not necessarily obeyed - moral imperatives (Prince and Geissler, 2010). Their relationships as clan members, friends or neighbours require them to respond personally, and to explain why KEMRI-CGHR and CDC cannot provide help with more basic needs such as clothing and food. Interestingly, in giving such explanations, VRs talk about how help could be construed as 'coercive', paraphrasing the concerns with 'undue inducement' voiced by ethics guidelines, to which they were exposed during initial training and orientation.

The challenges identified in this chapter warrant more in-depth examination than I have been able to give them here, including further dialogue with CIs such as VRs on how to address the challenges they face in practice. The fact that they face these challenges may also mean that they are doing a good job and are engaging both with their communities and the KEMRI/CDC research programme at a deep level. They are people who care about the issues and problems which arise in the implementation of research at community level. Even though more research would provide greater insights the findings and analysis presented here have both practical and theoretical implications.

On a practical level, closer working relationships between FWs and VRs should be fostered at KEMRI/CDC, coupled with greater communication between trial teams and VRs regarding the design of CE strategies. Clarifying the nature and ambit of VRs' involvement, and their rights and lines of communication, are also necessary; not least, to ensure that the value of the 'VR system' outweighs its potential disadvantages. Theoretically, we need to consider how to deal with the more problematic aspects of relational ethics in the context of CE - especially questions of undue influence and cultural and familial insider-obligations in the context of CE. To ensure continuity of good relationships between CIs and researchers it is also essential to develop our thinking further about how to manage both vertical and horizontal power relations in the conduct of trials.

## Chapter 8:

# Community Advisory Board Members' Perspectives on CE

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*'What I know the, when you want to be with the community, your entry point will be the village elders, through the assistant chief or chief. And then even the unlearned ones, when they hear something like research, they will always go to somebody who is a bit enlightened to ask, we hear that this is coming, is it good? So me I know the communities will always look for an influential person, within the community, in their locality.'*

**Female CAB Member, CR 07**

## Introduction

This chapter is very closely connected with the previous chapter since it relates the experiences of another community intermediary associated with KEMRI/CDC. Hence the literature review at the start of chapter 7 about community involvement and relational ethics is also of relevance here. A key difference between CAB members and VRs however is the fact that CAB members are volunteers in the strictest sense. They do not receive remuneration for their activities and their role is primarily advisory rather than being enlisted to promote research inroads into villages.

In this context it is important to remember that the terms 'volunteer' and 'partnership' can deflect attention away from the hierarchy and dependency which can underlie relationships, particularly relationships which are characterised by differential access to knowledge and resources. The use of the term 'volunteer' suggests that CAB members are free agents when in fact their autonomy is tempered by the fact that the CABs are set up and coordinated by KEMRI/CDC. This configuration suggests that researchers can exert some control over bodies set up to represent community voices. Nevertheless community members were and are very keen to become CAB members and gain access to KEMRI/CDC.

To present the institutional framing and personal perspectives of CAB members I draw on extensive field work carried out with the Kisumu and Karemo CAB at KEMRI/CDC from June 2007 until December 2009. During this period I attended numerous meetings convened for

both CABs, accompanied them on visits to other research institutes and to KEMRI/CDC facilities both within SDH and at the main KEMRI/CDC field station at Kisian. I visited CAB members in their homes and joined meetings they organised for the person responsible for community liaison for the RVT and MVT. In addition I spent a lot of time with this staff member in her preparations for and her interactions with CAB members. I also reviewed relevant documents which outline the role and function of the CAB and was able to read and analyse CAB members' reports on their activities. Finally I conducted two focus group discussions and 7 semi structured interviews with Karemo CAB members.

A key finding which emerges from this chapter is the concept of 'positioning' and how it applies to CAB members. Positioning enhances status, it provides access to new information and it can facilitate the implementation of research. Simultaneously it challenges notions of allegiance and accountability, and raises questions about how respect, influence and trust shape community opinions about research.

## **Institutional Framing of CABs at KEMRI/CDC**

CABs are a fairly recent form of community representation at KEMRI/CDC. The first CAB was set up in 2004 and now there are 4 CABs functioning in the main areas where KEMRI/CDC conducts research: Asembo, Gem, Karemo and Kisumu. The Kisumu CAB mainly supports HIV-related research taking place in urban and semi-urban communities. To date only the Karemo CAB has collaborated with KEMRI/CDC in the implementation of vaccine trials. Historically CABs at KEMRI/CDC have tended to be established to support preparations for and the implementation of specific trials. This was the case in Karemo where the CAB was set up by the RVT team several months prior to the start of the trial.

*'Well, you know this was one of the first vaccine trials that CDC here has done and looking at the ways to work with the community, to make sure that we didn't violate anybody's rights or, to know that we are approaching in a way that the community would be responsive to, ok. And of course if we were doing something that results, maybe something that the community would take offence of, ok, we wanted to avoid those issues and of course yeah, it seems like a good idea in general to have representatives in the community giving you feedback.'*

*Male American Trial Manager, RS 03*

In the planning stages the American trial manager and field coordinator sought advice from other research groups at KEMRI/CDC who had experience in running a CAB. They searched the literature on CABs and discussed how to proceed with the community liaison officer (CLO). They chose a model which would facilitate a broad representation of the Karemo population. They explained their intentions to the four Karemo administrative chiefs and asked them to organise barazas, which would provide a platform for sharing information about the RVT and identifying potential CAB members by means of a community-led nomination process. I attended one of these barazas during my first field trip in February 2007 and appended field notes describe this nomination process (Appendix I, Doc. 3). My observations reveal how researchers sought to control this initial encounter with the local community.

KEMRI/CDC CABs generally have a membership of 16-24 with a fairly equal gender balance, although the elected chairman is usually a man and the secretary a woman. CAB members elect their own committee which includes a chairman and a secretary, and sometimes an organising secretary and a treasurer. The purpose of a CAB depends in part on why it was formed and purposes can vary at different time points. The first CAB was set up in Asembo and was initially formed in order to provide researchers with feedback on questions to be used in a survey on sexual behaviours. Progressively however a more generic CAB model evolved with the objectives of serving as: a means of community entry; a way of gaining input on aspects of study development and implementation; a way of hearing about community concerns; a means to respond to concerns; and a platform for sharing and disseminating information.

The schedule for CAB meetings changed from monthly to quarterly half way through 2008. This decision was taken centrally to reduce costs in view of broader funding concerns. Quarterly meetings are paid for by KEMRI/CDC base funding and it costs approximately Ksh 20000 (£150) to hold a meeting. The change in schedule has resulted in packed agendas and limited opportunity for discussion and questions. To obtain more specific feedback some researchers organise additional CAB meetings which they pay for separately. Although the cost of these meetings is relatively negligible in terms of trial budgets it is a significant amount in the local context and can be difficult to justify under central funding agreements.

The mission statement of the Karemo CAB as cited in a CAB member appointment letter is *'to foster partnership between KEMRI/CDC research team and the local communities participating in KEMRI/CDC conducted studies to benefit advancement of research and the community'*. This statement implies that benefits to both the community and the research are expected as a result of this collaboration. The appointment letter is an official document which refers to the role of a CAB member as 'a job' but makes it clear that this appointment is not salaried. The only remuneration CAB members receive is a sitting/transport allowance of KES 400 to attend meetings. CAB members certify that they accept these terms and the letter is countersigned by the CDC Director. Appended is a copy of an appointment letter since it lists the CAB functions and CAB members' responsibilities in detail (Appendix II, Doc. 5). In short CAB members are expected to *'serve as the ears and voice of the community and study participants and help researchers ensure that community members at all levels are involved in the research process and that cultural differences are respected'*. They are required to *'serve as a resource, attend meetings and training and demonstrate commitment to developing an understanding of issues where they may have little expertise'*.

The groups mainly represented in CABs at KEMRI/CDC are: women's groups, boda boda (cycle transporters) syndicates, church leaders, retired teachers, business leaders, community health workers or nyamrechwe, community-based organisations, youth groups, disabled groups, opinion leaders and health workers. In regard to this idiosyncratic membership it is not clear why these groups are prioritised over others. Of interest also is the fact that the Kisumu CAB includes representatives from HIV advocacy groups and the Muslim community.

CAB members' backgrounds, life experience, social class and educational and professional achievements vary but they are required to have a working knowledge of English. CAB meetings are held in English and CAB members are sometimes asked to compile brief written reports on their activities and community feedback. CAB members enjoy vested or commanded respect of the designated groups and communities they represent. They are those who either: hold an official position (i.e. chiefs); whose knowledge, experience and age is respected; whose association with a faith group gives them moral standing; or whose



activities promote local investment and social good. They are viewed as opinion leaders with differing spheres of influence. The following definition for an opinion leader was given to me by a chief from Karemo, who is also a CAB member: *'This is somebody whom the community has faith in, seek for advice from him at their highest point of need after which they get to believe what he/she says concerning matters of development in the community'. (CR, 05)*

CAB members receive regular training about the role of CABs, trials and related procedures and research ethics. Training materials are mainly sourced from collaborators at the CDC offices in Atlanta. CAB members also visit the research facilities at the KEMRI/CDC field station and the research clinics and laboratories based at their local health facilities and hospitals. The Kisumu CAB has also visited another CAB at the US Army Walter Reed Research Station in Kericho, and joint meetings between different KEMRI/CDC CABs have taken place.

A spirited discussion about internal power relations within the CAB occurred at a joint meeting between the Kisumu and Karemo CABs. To situate this discussion it is important to point out some differences between these CABs. The Kisumu CAB represents a city, mainly deals with HIV research and has been in place since 2004/5. In contrast the Karemo CAB, which was established in 2007, deals with a broader programme of research activities and its members mainly come from rural areas although a few live in Siaya, the main town in Karemo.

At their joint meeting one to the Kisumu CAB members questioned the appointment of chiefs as chairmen for the Karemo CAB. He argued that in rural setting chiefs carry a lot of official weight which could compromise their ability to serve in this capacity. He explained that teachers could not chair school management committees and called for an official policy on who can chair CABs. In response both Karemo CAB members and the community liaison officer (CLO) stressed that it was CAB members' decision to appoint chiefs as chairmen. The Karemo CAB members stated that they were appointed by virtue of their personal leadership skills and not because they were chiefs. Another Kisumu CAB member did not think this was a major issue as long as the election of chiefs to the position of

chairmen constituted a unanimous decision by all CAB members. This incident led to some reflection about questions of autonomy, authority and leadership, leading one Karemo CAB member to remark that *'to a certain extent the spirit of chieftain is retained and as a CAB we are at the pilot stages of our work'*.

### **Different Conceptualisations of CAB mandates**

As outlined above the CAB model applied at KEMRI/CDC is geographic, institutional, collaborative and advisory. CAB members represent different groups from defined geographic areas in which KEMRI/CDC is conducting research. The model is institutional since, to all intents and purposes, the CAB is hosted and financed by the institution. It is collaborative since it aims to foster closer partnership between KEMRI/CDC and the local communities in order to advance research whilst simultaneously benefiting the community. Finally is advisory since CAB members are required to advise researchers in the development and implementation of recruitment and retention strategies, and serve as a resource to the CLO and research teams.

Despite the collaborative ethos of this model the impetus for setting up and resourcing CABs originated from researchers. This raises questions about the independence of these boards. It could be argued that paying volunteers an allowance engenders or implies a certain level of control or governance. In other words CAB members become more accountable to KEMRI/CDC than to the community. Such concerns have been voiced within the HIV research branch of KEMRI/CDC. Staff members responsible for community liaison within this branch have been keen to enhance the Kisumu CAB's neutrality in order to increase the CAB's credibility in discharging its mandate, to encourage it to function more independently, and to reduce overreliance on institutional support. The latter is welcome from a budgetary perspective since it can be difficult for KEMRI/CDC to secure funds for CE activities which are not directly related to trial recruitment.

In 2007 HIV research branch staff members suggested that the Kisumu CAB should register itself as a community based organisation, and KEMRI/CDC offered to support this process. The vision engendered was of an autonomous CAB which could apply for funds and

eventually be able to support itself thereby gaining more credibility as a representative body. The following comment made during an email exchange between myself and a Kenyan member of the HIV research branch illustrates some of the rationale behind this move.

*'They say in Africa that you cannot bite the hand that feeds you. Given that the primary objective of this CAB was to be like the eyes of the community in research activities, do we expect them to reprimand, or even question the researcher if they are hosted by the research institutions, given refreshments, lunch and transport reimbursement for their meetings amongst other indirect benefits?'*

Whilst Kisumu CAB members were enthusiastic about this vision they also expressed reservations about assuming long term responsibility for running costs, calling and managing meetings. Some CAB members ran community based organisations, but they mainly attracted funding for charitable projects rather than for advocacy activities related to research.

At the height of these discussions about autonomy in 2007 a French HIV activist visited the HIV research branch in Kisumu. She was travelling on behalf of the non-governmental organisation 'Sida Action', which is a contested group within the world of HIV advocacy (de Cenival, 2008). The purpose of her visit to Kisumu was to stimulate support for a more far-reaching change in the purpose and organisation of CABs. With the permission of the HIV research branch chief she met the members of the Kisumu CAB to find out more about their role and responsibilities and to communicate Sid Action's broader vision of establishing community-based ethics forums. She explained that these forums should be autonomous advocacy groups which could hold researchers accountable. She argued that this kind of forum would be more productive than having several smaller CABs hosted by research organisations. She urged the CAB to talk to members of other CABs based in Kisumu about developing such a forum. During their discussions she also asked the CAB members about peer recruitment strategies employed by other research groups working in the Kisumu area. The CAB members were willing to discuss related ethical concerns; however they also exercised restraint in their answers and were evidently uncomfortable about criticising other research groups. At the end of their meeting the HIV activist handed out business

cards and told CAB members that if they were interested in developing a community ethics forum they could apply for funding from Sida Action and other HIV advocacy groups.

Whilst the idea presented by the HIV activist reflected some of the concerns raised by KEMRI/CDC staff about the independence of CABs hosted by research organisations, it represented a more audacious vision of community advocacy and political activism. In essence two new conceptualisations of a CAB or a community representative body were being proposed. The first involved the existing CAB registering itself as an autonomous body with the city council, which would enable it to apply for funding for its activities and enhance its impartiality. Collaboration with KEMRI/CDC would still remain a strong feature of its purpose but the basis for collaboration would become more equal. Essentially the CAB would take on more leadership in this CE exercise. The second conceptualisation was of an independent politically orientated and activist community ethics forum which could demand closer accountability from any researchers working within a stated geographic location. This would require existing CABs to amalgamate, sever direct links with research institutions and formulate a new mandate.

In practice it has been very difficult for the Kisumu CAB members to realise either of these proposed ways of increasing their autonomy. Endeavours to pursue registration as a community based organisation were met by a lot of governmental red tape and currently they are considering registering as a society. A society is a professional body whereas a community based organisation mainly deals with problems affecting people in a specific geographic area. Community based organisations generally have broader mandates, attract more funds and have more scope to take action.

To date the CAB has not pursued the idea of amalgamating with other CABs to establish a more activist forum, and as far as I am aware there has been no further communication from the HIV activist about this proposal. The HIV research branch has also started to pursue more research activities in rural areas (Asembo/Gem/Karemo) as opposed to Kisumu which has resulted in reduced engagement with the Kisumu CAB. These questions about autonomy and the positioning of CABs remain of relevance at KEMRI/CDC even if it is unclear how to resolve them.

## **Karemo CAB Members' Perspectives**

As indicated in the quotation cited at the start of this chapter CAB members are usually people who command or enjoy a certain level and manner of respect at community level. They describe themselves as people to whom community members normally turn for advice or guidance in relation to questions of personal or public importance. The reasons people turn to them are varied and include seeking reassurance, wanting the benefit of a different and possibly more *'enlightened'* perspective, wanting to know the range of opinion on certain issues, and looking for resources and connections. The notion that some people are more enlightened than others is very common in the rural areas where I undertook my field work. Those considered to being enlightened are those who have benefited from a good education and may have spent some time away from the locality for the purpose of work or study. This term was also frequently used by people of a higher standing to distinguish themselves from subsistence farmers and petty traders. CAB members may be considered to be enlightened and they definitely possess a certain status which can be attributed to their age, education, position, business skills and/or inherent leadership qualities.

With regard to this notion of status it is important to think carefully about why people are respected. Is it due to their social standing; is it because they are a recognised authority (which may not necessarily be assumed to be benevolent); or is it because they are known to be people who make things happen and are not afraid of voicing their opinions? Or are certain people respected and trusted on the basis of personal ties or kinship relations? The reasons why individual CAB members are respected within their respective groups and communities vary and some CAB members may engender more respect than others, simply because they hold recognised positions - e.g. administrative chiefs. Some CAB members may also not command the respect of all members of their communities - e.g. youth leaders may not always be fully respected by their elders.

The Karemo CAB encompasses a wide range of people including retired teachers, a blind advocate for disabled people, two chiefs, and representatives from boda boda syndicates, youth groups, traders, churches, community based organisations, and women's groups. These people share in common the ability to communicate freely and confidently with

KEMRI/CDC staff. They are also willing and able to set time aside for this voluntary work, and whilst not all of them are financially secure such constraints do not hinder them from being involved in the CAB. They are motivated by a desire for increased public access to treatment and health services, and value the opportunity to learn more about health, research and the way KEMRI/CDC works. One CAB member talked about his interest in the dialogue between the community and KEMRI/CDC and the way this can change perceptions about research. In the following three sections I will present CAB members' perspectives on their nomination, their role in CE and the questions they are asked.

### **Becoming a CAB Member**

*'It was about 2007 there, I think around February or March of that year. There was some mobilization that came from the office of the chief that the KEMRI/CDC wanted groups of people [mmm]. So we went [mm], and we found the CDC team there and they told us actually what they wanted to do [mmm]. So they wanted us to be in our respective groups [mm], so we were classified according to the groups that were there for example the women's groups, the community based organisations [mm], the boda boda traders or the bicycle transporters, the retired teachers and so forth. So, we were told now to have representatives from each group, there was a nomination from each group [mmm], then later on, there was an interview carried by the CDC and from that interview, I mean up to the nomination, we were about fourteen or so people [mmm], then we were called for the interview and finally I think they came out with six or seven people who qualified [mmm]. So that way we became CAB members [from Siaya town], yeah, that is from Siaya.'*

*Male CAB Member, CR 06*

This quotation describes the CAB nomination process which took place at barazas across the four main locations in Karemo in 2007. Chiefs were asked to alert community members in advance that KEMRI/CDC was looking for community representatives from different groups within the locality. When people heard this they were keen to come and find out more; according to one CAB member some even thought this might equate to an employment opportunity. At the barazas a team from KEMRI/CDC introduced the RVT and then explained that they wanted to form a CAB and what this meant. The nomination process was a fairly informal affair which took place in small groups and was decided by a show of hands. The names of those nominated by their peers were then passed on via the chiefs to the

KEMRI/CDC team during the same baraza. In some instances groups nominated people who were not actually present at the baraza. In these cases the chief checked with the individual in question and then passed on their details to KEMRI/CDC. The CAB members I spoke to were proud of having being nominated and viewed it as an honour that was in part due to their good public relations. One CAB member said she faced stiff competition and was glad that she made it, while another stated with satisfaction that *'it was not easy to get here'*. The nomination process was also described as a ticket to an interview something they won and were very proud of, something that provided them the opportunity to gain access to KEMRI/CDC.

*'So that one gave us a ticket to interview [eeh], then for those of us who won the ticket, you were given a date [ok], for the interview at the chiefs camp [right] yah. So at the chief camp is where we were told, do you know that CAB will be voluntary [eeh], and do you accept to do voluntary work [eeh], as per now what are you doing for a living because we don't want to interfere with whatever you are doing because this will be a free thing.'*

*Female CAB Member, CR 08*

[Interestingly in chapter 10 this concept of gaining access recurs when mothers of RVT participants ask if they can be give a gate pass into the MVT which was about to start. These mothers wanted to continue their association with KEMRI/CDC and to continue to benefit from the larger project.]

It was evident that even though the work of CABs is voluntary those nominated were keen to be accepted as CAB members. The interviews were conducted by the female Kenyan community liaison for the vaccine trials and a female American study coordinator for the RVT. They took place at the four chief's camps across Karemo division. CAB members described these interviews as informal discussions in which KEMRI/CDC representatives sought to ascertain whether nominees understood the purpose of the CAB and would be suited to this role. Those who passed the interviews successfully took part in training on the function of the CAB, the conditions and responsibilities of membership and the RVT. Initially the selected CAB members mainly supported the RVT, but later their role expanded to providing input on other studies.

*'Yes, you see us, first um we knew about the rotavirus, we thought our CAB was made to be for the rotavirus project... we were trained on the Rotatec (the vaccine), the Rota virus and we were also told the target group of the study and then we thought that it was only a CAB for the Rotatec, the Rotavirus. Then, later on we came to learn that it was a whole community CAB, where anything, any project, any study that would come through CDC would pass through.'*

*Female CAB Member, CR 02*

CAB members conveyed a considerable measure of self confidence and described themselves as leaders to whom others listen and come to for advice. One female CAB member (CR 8), who is also a local councillor, described herself as 'exposed' meaning that she was not inhibited about speaking out in front of authority and strangers. She was literate, but more importantly had life experience and knowledge partly gained from having lived in Nairobi. Therefore she was not impeded by cultural norms which can hinder women from voicing their opinions.

Whilst CAB members were assured of their status within their own communities it was also apparent that their association with KEMRI/CDC changed how people viewed them and raised certain expectations. Although they continued to be viewed as valued sources of information people also thought they were earning a lot and would refer to KEMRI/CDC as 'this, your people', asking them tongue-in-cheek, 'what do you think about these your cars?' Overall however CAB members' status and pre-existing relationships enabled them to listen to concerns, provide information and allay anxieties.

*'Our area, and of course you see, the good thing was that the people who were actually elected and finally selected to become CAB members are actually people who people listen to [mmm] within the community. I sit here people want to ask me questions. People are desperate they really want to believe me, it helped a lot. They come along and really want to verify whether what they are hearing, what's said, is true or false. So, I just make the record straight and once they go out, they are satisfied, yeah.'*

*Female CAB Member, CR 02*



## **CAB Members' Role in Community Engagement**

*'How will you work without people? You are working in their area and you are working alone, if they'll just stand and look at you and after all when you leave they'll come closer to see what you are doing there and maybe spoil it. If you don't involve them even if you put water there they will not come and use that water, so they have to be involved.'*

*Female CAB Member, CR 44*

### ***Understandings of community engagement terminology***

In the early stages of my field work I asked CAB members to define the terms 'community', 'community engagement' and 'ethics'. On an arranged day in November 2008 I invited them to a meeting at which I provided an overview of my study with opportunity to ask questions. Towards the end of this session I gave them each a piece of paper and asked them to write down what they understood the three terms to mean. Their interpretations of 'community' were very similar and placed emphasis on the following characteristics people who lived together, shared a geographical space, had common interests and goals, shared the same history and culture, had common beliefs and values, worked together and shared common resources.

The notion of commonality was very strong in these definitions and only one CAB member introduced the idea of difference within her definition. She said: *'a community is a group of people living together with different tribes, culture and ethics'*. Of note is that this person lives in Siaya Town which has a more diverse population than most of the villages across Karemo. It includes people who have moved to the area from other parts of Kenya in the pursuit of work or who have been transferred to Siaya as policemen or health professionals.

CAB members' definitions of CE in this meeting were more varied and tended to stress the importance of involving everyone in the community to achieve a mutually beneficial goal (see Text Box 3). Participation and understanding were seen to be central to this activity. Only one definition focussed solely on communicating research messages; the others encapsulated a much broader agenda which in some ways was more closely aligned with community development.

### TEXT Box 3

#### CAB Members' Definitions of Community Engagement, November 2008

*It is getting together or being involved in some activities as a team.*

*It is the participation or contribution a community does in any study going around.*

*The relationship between the community and the activity taking place in the area for a purpose of finding problems and solutions to the entire community.*

*Community engagement is participating in communicating messages concerning research.*

*Inclusion of members of a particular community to undertake an activity that will benefit them.*

*The involvement in a project or a study of a given community.*

*Involvement of people in certain activities within a certain region.*

*This is a community who do their work together both skilled and unskilled e.g. a water project or bridge project involving all people without force. They are happy and willing.*

*It's an involvement of the community members in a certain project, positively to make it*

In subsequent interviews CAB members continued to equate CE with community involvement and participation, which are terms that are used widely in the development literature. CAB members seemed to draw on these ideas of team work and coming together to achieve a specific goal in their reflections on CE. They warned that if you do not involve people you could end up by spoiling your project. This is graphically illustrated in the quotation at the start of this section. However they also used these terms with specific reference to research by explaining how important it was for everyone to know about the research. For example one CAB member who is also a chief talked about how those with more formal education can help their neighbours understand the purpose of research and what it will involve for their children.

When it came to explaining 'ethics' CAB members referred to two aspects of ethics: the guidelines that govern research which they had been introduced to as CAB members; and 'chike' (cultural rules) which represent behavioural norms for the way you should live and relate to one another. The fact that there is no specific word for the term 'ethics' in Dholuo partly explains these broad interpretations; on the other hand even in English 'ethics' can be interpreted variously depending on one's perspective and purpose. In the field of research

ethics increasing attention has also been paid to the importance of accounting for and respecting cultural beliefs in the implementation of trials. Interestingly this aspiration is also evident in one of the CAB member's definitions of 'Ethics': *'It is harmonising the beliefs of a community or an individual with the guidelines of any research or any other institution undertaking anything involving them or him/her'*. This suggests that CAB members are right to have a broad view of ethics and they should help researchers think about how trials interact with cultural and social beliefs.

### ***Positioning: Providing safe passage***

CAB members, like VRs, also viewed their role as central to the practice of CE. They thought it would be difficult for researchers to operate without their support and argued that trials need to *'pass through the CAB'* before they commence. One of my interviewees stated that the CAB provided trials with a *'safe landing'* in a community which might otherwise be resistant to research. In the following quotation he described how KEMRI/CDC tapped into a pre-existing system of consultation and used this to its advantage.

*'You know in our place here, there is a lot of politics [mmm], and they wanted to involve CAB so that when they come, and more so that they are coming to do the research. They wanted to have a safe landing [mmm], so that the CAB people, like we call them opinion leaders, when the community run. You know when you are staying in a village like this, we normally have people which the community regards so much [mmm], if they have a problem, they run to them, they ask them, oh we've heard of this and that, are you aware of this? And then if that person talks negatively about that thing, [mmm] they will just automatically reject it [right]. But if they find the person is with that idea and then convince them, they now believe, so they have the people they believe on [ok]. Some people, these people are being found at the churches [yeah], the community, you know maybe somebody who is, who is more than, normally get in touch with the people and then help them some other assistance. You find those kind of people are the people who are normally being elected at the schools as the chairmen [yeah, I see], they are normally elected on the activities which they, so they regard them so much [mmm]. That's why when the KEMRI/CDC came here, and interviewed them, and involved them, now when they hear about the things, they run to those people and then they get the answers.'*

*Male CAB Member & Chief, CR 25*

Despite significant advantages this also raises questions about using trust as a lever for promoting community acceptance of research. CAB members did not comment specifically on this although they repeatedly stressed that their role did not involve convincing people to take part. Whether their association with KEMRI/CDC in and of itself did serve to allay the anxieties of those who turned to them for advice is, however, an open question.

***Positioning: Balancing allegiances***

*'People were fearing that these are NGO's that were just coming here to cheat, cheat people... but me I was very firm and even talked it out at the chief's Baraza. I said that CDC has worked in the area I come from [mmm], me I am "Nya Sembo" [a lady from Asembo] and CDC has worked at our place [mmm], and people were given free nets [mmm], and they said bye to mosquitoes [mmm]. So it has nothing to do with the conning people [eh]...there were a lot of rumours, but still I stood firm telling them that CDC has done a lot from even where I come from*

*Female CAB Member, CR 08*

The notion of standing firm expressed in this quotation is of interest as it suggests that CAB members take positive action to promote the work of KEMRI/CDC. It describes how association with KEMRI/CDC can result in a CAB member's balance of allegiance shifting from the community more towards the research institution. In this quotation the interviewee draws on her past experience and current dealings with KEMRI/CDC to refute rumours or questions about KEMRI/CDC's intentions. In the interview she talked about how her mother had been a VR with KEMRI/CDC in Asembo in the early 1990s and how as a family they had benefited from the Saradidi community health and development project. This went some way towards explaining why she felt so positive about KEMRI/CDC. In terms of her prior understanding and experience of KEMRI/CDC she was atypical. She was not atypical however when it came to how CAB members viewed their responsibility of presenting KEMRI/CDC in a way that would help to overcome suspicion and promote acceptance. Similar ambitions were evident amongst VRs who were keen to present KEMRI/CDC as being different from organisations which prioritise self gain over community benefit.

CAB members take 'being' with CDC very seriously; it has become important to their identity and positioning. They are happy to be associated with CDC and the modernist project of health research and can be zealous in their support of KEMRI/CDC. They are keen to defend modern and what they perceive to be good values. They do not want to revert to the old ways but want to be associated with the new, and they seek to encourage KEMRI/CDC to extend their influence and do more to contribute to their communities. Hence although some CAB members do offer critique overall they are more vocal about the need to extend research and related health services. With regards to critique it is also important to consider whether critical thinking or questioning of recognised bodies is common or well-developed in rural Kenya. The education system does not teach problem-solving skills and students are encouraged to respect authority and follow instructions. Whilst this does not always quell initiative and ambition it can foster undue deference to strong leaders, powerful bodies or those who are perceived to be 'enlightened'.

### ***Positioning: Role and inherent ambiguities***

When CAB members explain their role they tend to repeat certain figures of speech and terminology which were used in their training to illustrate the purpose of the CAB. These terms are '*the eyes and the ears*' or the '*eyes and the voice*' and '*the bridge between researchers and the community*'. In the following paragraphs I trace different applications and interpretations of these terms and seek to convey some of the ambiguity which surrounds the role played by CAB members. On the next page I cite the terminology as given in the CAB appointment letter (Appendix II, Doc. 5) and CAB training materials (Appendix II, Doc. 6) on the left side and on the right I present an extended interview excerpt to illustrate and contrast how this terminology is applied in practice. I then reflect on the contrasts and ambiguities revealed therein.

**CAB Terminology as cited in  
KEMRI/CDC Documents**

*'CAB members serve as the ears and the voice of the community and study participants.'*

*'CAB members will listen to the concerns of the community, with regard to CDC and the research project.'*

*'CAB members will inform the research team of the concerns.'*

*'The members of the CAB and the research team will work together to come up with possible solutions for the problems.'*

*'The main reasons for having a CAB are to build a bridge between the community and the research staff... and to serve as the voice of local questions and concerns throughout a given study.'*

*'The CAB functions as the primary link between the community and the study research team.'*

*'The CAB is responsible for disseminating study information to the community.'*

**Interview Excerpt, Female CAB Member,  
Area 4, CR 08: Role of the CAB**

Ok, so, just tell me what you think the role of a CAB member is, just in your own words, what is a CAB member responsible for, what are they supposed to do?

*'CAB members, we are just an ear or eye of KEMRI/CDC.'*

What does that mean, [ear and eye] yeah, what does that mean?

*'We hear for the CDC, we see for the CDC before they come to the ground [mmm], we are just like a bridge [mmm] mmm, a bridge between the village and the CDC.'*

So, how do you do that?

*'I do that for example when there is a research like the last one of the rotavirus [mmm], it was very clearly said at the baraza [mmm] mmm, so now the CDC also had to also call us for a meeting or a seminar that we normally go to so that they give us our roles [mmm], as CAB members, we want you to go to the ground or to the village, tell these people that we want to do the research and this is the research [mmm]. And it will take from this year to this year [mmm], certain age to a certain age [mmm] [yeah, yeah]. These are the dispensaries or the hospital which the research will be done [mmm]. So you know they can't reach everybody in the village [mmm, no], they go through us [ok] and we come and tell them [ok], that the CDC are going to do the research, you see. Here, it will be done at Ngi'ya or at Siaya, there will be a fare reimbursement [mmm], you will not just walk on foot [mmm] to and fro. You will come back and with your child, is which age, one year or six months? Then he is good for the research [mmm], take him, ok these disease, ok the research is to prevent this and this, to prevent the child from diahorrearing, from vomiting and at least to prevent them from the earlier death. So that is what was our role, just to come back down to our people [and talk], and talk to them [ok] mmm [sawa ok].'*

Discrepancies are evident in how the figurative term 'ears and voice' is described in the KEMRI/CDC materials and how it is interpreted in practice by the CAB member cited on the previous page. Officially this term is used to illustrate CAB members' responsibility to listen to what community members are saying about research and to relay any concerns to researchers. But the interviewee adds a slightly different slant to this by claiming that CAB members are 'an ear or eye of KEMRI/CDC'. Implicitly this interpretation changes how CAB members are positioned in regard to the community and KEMRI/CDC. It suggests a more proactive role than just communicating community concerns and thinking about solutions. Indeed the CAB member presents herself as part of the solution. She attends seminars run by researchers and then she goes down to her people and talks to them about this research (in fact she says that she is told to do this by those running the seminars). She helps to bridge the gap between the village and the researchers, she shares information and she encourages people to come to the clinics where the research is taking place. If we review all the responsibilities assigned to CAB members one could argue that this is a valid interpretation since, after all, they are asked to disseminate information about studies at community level. What is not specifically spelt out however is whether this is to raise awareness and canvass opinion or whether it is to encourage participation, and how one differs one from the other. Other CAB members understood their responsibilities for communication as entailing being the ear for both the community and the researchers. They describe themselves as go betweens, those who are positioned between the community and researchers and who relay information from one to another.

*'I attend the meetings the CAB meetings I get the information of what CDC want to do I come back to the people and tell them what is going to happen and if they have any questions I take back to the meeting and we write in reports whatever we hear we write in our reports and we take to the meetings (okay). I was like an ear for the CDC in the community and an ear to the community in the CDC meetings.'*

*Female CAB Member, CR 44*

*'...as a CAB member, mostly I am here to, I am here just as an eye of the KEMRI/CDC or I am here to link the two people together. I am between them, if there is a problem in our area, I will take it to the KEMRI/CDC when we meet. I will give them the problem or anything that is ought to be done, we will share the ideas together to help the, any situation... So I am there to help the community, if there is any problem, I raise it up. I make the communication become cheaper between KEMRI/CDC and the community.'*

*Female CAB Member, CR 04*

This positioning is however not always comfortable and ambiguities relating to their role were also expressed by other CAB members. Many were unclear about their role, what they should do and how open they should be about their activities. One person even described their activities as slightly clandestine.

*'CAB members you know they should be just like a spy, somebody getting something from a project or getting the views of the people against or pro the project and then you give a direct link to the researcher that should be the main work of a CAB member.'*

*Male CAB member & Chief, Area 2, CR 05*

This quote essentially describes CAB members' responsibility of informing researchers about community concerns. CAB members were not asked by researchers to act as spies but they were also asked not to be too zealous in their representation of KEMRI/CDC. The turn of phrase chosen by CR 05 does however communicate some negative associations with working undercover and disclosing sensitive information to outsiders. What is interesting is that this person is well known at community level and his links to KEMRI/CDC were not concealed. He was also very proactive about organising public forums for researchers to respond to particular community concerns when they arose. Nevertheless the sub-text suggests that operating as a go-between for researchers and community members is not always comfortable. CAB members can be unsure about how to position themselves and whether or not to 'expose' themselves: i.e. whether to tell other people that they were acting as CAB members. Of note is that the use of the word 'exposure' here is different than its use as a way of describing how attachment with KEMRI/CDC provides CAB members or VRs with new experiences, or how living elsewhere can increase one's understanding of the world.



*'Ok, in after the first meeting we were not told to expose ourselves, yeah, so the community didn't know what we are doing... so they can just talk and you get what is in their hearts or what they are feeling so when this rotavirus was introduced they could talk; me I can't take my child they are going to misuse my child, me I can't take my child for research I don't know what will happen after 2 years or 3 years. So they can talk and you get the information because they don't know you are connected with the CDC and that's how we were getting the information and taking to the CDC on the meeting day. So it was somehow an advantage being private because now they can say it openly.'*

*Female CAB Member, CR 16, FGD*

Questions about exposure and positioning stimulated an animated debate in a focus group in which CAB members talked about how they should present themselves at meetings, and whether they should speak out as CAB members or just put forth their opinions as community members. The discussion also raised questions about what they should or should not do as CAB members. Focus group participants explained that initially they were constrained in terms of what researchers wanted them to say or do. Researchers were hesitant about their ability to answer questions about the research and therefore only wanted them to pass on the information given to them. As the trial progressed researchers did engage their help to organise forums but their role was to facilitate information exchange and not to speak in public forums on their own or convince or encourage people to take part in research. Some of the CAB members expressed frustration about a desire to be more actively involved in promoting KEMRI/CDC.

This exchange touched on what it means to mobilise the community. Whilst CAB members' mandate does not officially cite mobilisation as one of their responsibilities, CAB members equated disseminating information and assisting in education activities with mobilisation. The following excerpts present two differing interpretations of mobilisation.

**Interview Excerpt (Female CAB member, Area 1, CR 2): What is Mobilisation?**

**CR 2:** *Normally when we get to the CAB meeting, there are normally sessions where each location comes with their issues, their concerns and then they are written on the wall, wallpaper or newsprint, then they are discussed by everybody. Then we go to, ok we get a way forward, we make suggestions, and even if it means now the KEMRI/CDC, whoever, they must go back to the community. Then we help mobilize, that is the way through, the way out, the only way out, we help mobilise and they come back again as a team, we go now again to the community.*

**I:** *When you talk about mobilising as a CAB member, what do you mean?*

**CR 2:** *It was like now, if it is my group, our members like the community based organisation, they may have issues that I may not be able to answer. If I make a report there, we make a work plan and we got that on Saturday, they will come to SWYND (name of community based organisation), and meet with the SWYND members to clarify those concerns that I took from there.*

**I:** *So in that sense, it is not that you were mobilising the people to take part in the study, you are just creating opportunity for people to talk?*

**CR 2:** *Exactly. You see with this kind of study the way we were trained, you just give people information, you get them, you talk about it, you are conduits...*

**Excerpt from Field Notes, written after a first meeting with some CAB members from an urban area in January 2009:**

**What is Mobilisation?**

*The second question was about the role of a CAB member. The typical answer was cited: 'CAB members are a bridge between the community and CDC'.*

*Again I probed further on this later, and asked them in particular what activities they get involved in. The term 'mobilisation' was mentioned and I asked them to explain what this meant. The boda boda representative said it '**involved convincing people to take part in the study and the others agreed with this definition**'. I checked this again with them but they definitely viewed this as part of their role. The disabled group representative talked about the fact that they are told things in CAB meetings that now need to be shared with others; they are channels of information.*

There is a fine line between when sharing information becomes recruiting, encouraging or even convincing people to take part in trials. Even though most CAB members stated clearly that they were not supposed to mobilise people in the sense of recruitment, many of them did talk about encouraging people to take part in trials during interviews and focus group discussions.

***Positioning: Changing people's thinking about research***

One CAB member explained how the dialogue between researchers, CAB members and community members helped to change the way people think about research. He explained that *'the question of research was polluted people feared research in the past and thought that the risks were very high and that researchers were out to gain from you'*. He and others described how interaction with KEMRI/CDC both through CAB members and in observing research taking place in the community resulted in a change in people's thinking. Community members became accustomed to research because of what they saw happening and their interchanges with CAB members, VRs and KEMRI/CDC.

CAB members primarily focussed on their role in information exchange and spoke less about how they advised researchers and even less about bringing community priorities for research to the table. Only one CAB member mentioned the latter and it is important to clarify that this person was an active advocate for disabled people's rights. He ran his own community based organisation, was very articulate and thought carefully about broader issues for example support for indigenous research at a national level. He proposed that space should be allocated to bringing community ideas and research priorities to the table. He referred to health problems which were affecting local people and for which they would like to see a solution, questions relating to learning disabilities and other diseases. His stance was that CAB members and other community representatives could be and should be more active in forming the research agenda. Others differed and questioned their own and community members' capacity to shape the research agenda and advise researchers on technical issues.

*'How will they know what they want to be researched on, they are not researchers they don't know what is happening, like now the swine flu, would they know if they are not*

*told? So I don't see the community deciding on some research that they want to do, but if there is, they should say it, they should go to KEMRI or CDC, they make this research done here.'*

*Female CAB Member, CR 44*

The content of this section suggests that community members are becoming more familiar with the practice of research and less sceptical about the intentions of research. At the same time research remains a sphere which is led by experts and which community members and even CAB members do not feel equipped to influence directly.

### ***Positioning: Relationships with others and questions posed to CAB members***

In contrast to VRs CAB members are less involved at household level, and do not encounter the same kinds of requests for assistance. Community expectations are not directed at them as individuals; however they are asked to encourage KEMRI/CDC to do more. Occasionally someone will ask them to buy them a soda since they are 'working' for CDC, but overall they do not encounter or need to balance the same obligations as VRs or FWs in the execution of their duties.

CAB members argued for closer interaction with FWs and VRs and thought that this will strengthen CE. Some of them already worked closely with VRs from their area but most had limited contact with FWs. If rectified they believed that closer contact would help them address community questions. They could also link up FWs with people raising specific concerns which would help to reduce speculation and improve community relations.

Initially the questions people posed to CAB members focused on the nature of KEMRI//CDC activities. They wanted to know what to expect, and why KEMRI/CDC prioritised research and did not address more concrete needs.

*'The difficulty is that the people wanted to know what the CDC will actually do to them. There were a lot of questions, so we take the information from the community, we link them with the, give them to, to the CDC. But like now the people are, you see the people are aware of the activities, they were asking the people are they going to build our schools [ok], are they going to provide us with food when we are hungry, those kind of questions.'*

*Male CAB Member & Chief, CR 25*

Questions were most pressing in the early stages of the RVT, and waned off later. However as the following interview excerpt indicates some questions do not go away and form the basis of suggestion, storytelling and debate at community level. Storytelling was defined by one CAB member as a form of sharing information in an entertaining fashion. The following quotation describes this practice and outlines problems that CAB members can face when they seek to set the story straight.

**Interview Excerpt, Female CAB Member, Area 1, CR 02: *Storytelling***

*'Yeah, even in South Alego, we have the shopping centres where they can do read newspapers they can listen to their radios. But, even here within Township here, where you feel that it is not reserve, there are places where they don't listen to radios, they don't read newspapers. So it is very true a few people to go to those shopping centres to read and listen. But you see, around here, people around here are storytellers, they want to go back and give information that will make people laugh, because if people don't laugh, then there is nothing you have said and therefore, they will add a little salt, they will add a little sugar and then it will tell something very terrible even if it was good. That is actually what happens. So when somebody writes somewhere that somewhere in either in, either in Sudan, I don't know whether it is Sudan or Nigeria or somewhere, where I think some people went to do some research and um somehow the research made the orphans and children turn to be HIV positive and then they were chucked out of the area. That is what people are going down into the villages to say. Just like it happened there, that is what is going to happen here. So people would want to listen to such kind of horrid stories, you know, because they are about what they want to listen [Entertainment?] It is kind of, it is entertainment now. So you know the kind of message deliverer will strive to entertain this people even if he has to lie and make things bad and bad and bad. So you know if you have such kind of people in the village, and you are X (a CAB member), you want to go with facts, then you see you are in trouble because you will be dull. They keep on asking questions like you see, they take our blood but the syringe they use has been contaminated with the HIV vi, virus. So we found out that it was not really even blood, it was the matter of the syringe being contaminated, yeah. So, we had to like eh convince them like eh how can the syringe be contaminated because the syringe is filled in front of you. Yeah, go and ask the people who are actually participating, were the syringes filled in front of them or the syringe came already opened. Then slowly by slowly they listened and of course they were waiting to see whether today or tomorrow, a child was going to die because the child maybe was under that study but they saw none, yeah they saw none.'*

In the above social situation the CAB member found herself having to infiltrate popular banter in order to try to put the other side of the story across. In her interview she talked about how she met with storytellers in person to discuss the repercussions of their stories and to emphasise that KEMRI was a government organisation. As a result some of them changed their stories saying that they had been misinformed but this is now the truth.

CAB members are asked a wide range of questions by different people and some are approached directly by community leaders. For example, an Anglican clergyman sought reassurance that parents understood that trial participation is voluntary. CAB members can seek the support of the CLO and trial staff when questions pertain to technical issues, concerns about blood and requests for additional support such as medical camps and malaria prevention.

**Text Box 4: Types of Questions CAB members are asked**

*'Yah, the question that has really refused to go away is this issue of blood but I would say that it our culture. People simply fear blood, yah. In our culture, you don't just kill, people fear blood, so even if somebody sees a little drop of blood [mmm], they feel that that should not happen. And also, I think from other myths...'*

*'At first they were asking were, where we were taking their children, where the people who are in the study take their children and they also ask if there is something, there is any profit?'*

*'And then they will ask you how comes that every now and again the KEMRI is here, the World Vision is here, what is, what is their interest in our Karemo?'*

*Why this research, what is happening, why should we take our children for Rota virus and whatever? Why do they want children, they take blood of children what are going to do with the children? We understand they want to take these children to America? You know even when there was nini (what) this family planning earlier, people thought that they were going to make them sterile so even when this Rota came they were suspicious and they wanted to know why this Rota virus? Children have been having diarrhoea they are being treated, why is this nini now coming up, why do we need the vaccine, where had they taken it from?*

*'How come so and so has a child, the same age with the, that other lady. They both went to hospital to register ok to participate in the study, so and so's child was taken, so and so's child was left, why [laughter] yeah?'*

*'People are asking about what, they want are nets, when are we getting nets, why did these people get nets and we did not get? That home got a net, that home did not get a net, why?'*

*'Now they ask; why is it only for the women and the children and not for the old men?'*

*'When are they starting?'*

The sequencing of the questions in Text Box 4 shows how, gradually, people's attention is drawn more towards the benefits of trial participation. In a bid to negotiate trials to their advantage concerns turn to focus on exclusion rather than inclusion. This shift requires CAB members to explain why one child may be accepted for the study and another not and why recruitment may be limited to certain ages and have a finite number. More broadly this shift also charges those responsible for CE with the difficult task of addressing the boundaries which control resource distribution and research participation.

## **Discussion of the Main Themes**

CAB members presented themselves as a pre-existing network of community leaders whose opinions are highly valued by community members. By tapping into this resource CAB members felt that KEMRI/CDC has been able to gain significant insights which have helped smooth the passage of research. At the same time CAB members' reflections about their contributions also raise questions about whether their links with researchers have affected both how people view them and their ability to provide independent advice. Here again we encounter the double-edged sword of trust; on the one hand it facilitates positive rapport, on the other it may lead to undue influence. A fundamental question is: can 'trust' be an appropriate lever to use when seeking to promote community acceptance of research? We also have to remember that trust and respect can be invested into people for different reasons and respect does not equate with trust. One may respect someone because they occupy a position of authority but you may not trust them as an associate or friend.

CAB members highly value their association with KEMRI/CDC. They were proud to be nominated by their peers, to pass the interview and to gain access into a modern and progressive project. They described themselves as go-betweens, those who are positioned between the community and researchers and who relay information from one to another. CAB members' positioning emerged as a key theme in this chapter, which cut across many different aspects of their experiences. CAB members' positioning enhanced their status, it facilitated research, and it helped researchers appreciate contextual issues and address local concerns. At the same time it created challenges regarding CAB members' allegiance and the execution of their role. Significant confusion over the scope of CAB members' role was evident with CAB members occasionally having to take partisan action in order to

represent KEMRI/CDC's work accurately. However in other instances they were unsure about how much are they allowed to say and whether they should '*expose*' themselves as CAB members or behave more like '*spies*'. Some of these questions were resolved as the CAB became more established and members became more confident about what they could do, and when they should seek input from researchers. Other questions however continue to linger, particularly those relating to '*mobilisation*' and trial participation. What is the difference between telling people about research, gathering them to find out more and recruitment? In practice there are subtle differences in how different CAB members interpret their role, with some being more proactive than others when it comes to encouraging community members to participate in trials. The confusion that exists over the scope of the CAB role is not helped by the use of figurative terms such as *the 'eyes and ears'*.

In the first part of this chapter I recounted two new and different conceptualisations of a CAB. Both of these seek to increase the autonomy of such bodies and make them more accountable to the community. Neither of these models represents current practice at KEMRI/CDC even in the Kisumu CAB which is being encouraged to register itself as an independent body. The Karemo CAB was set up as one way to help prepare the community for vaccine research and ensure that participants' rights are protected. This CAB retains strong links to KEMRI/CDC and in essence CAB members function as recipient and conveyers of information and community feedback. Very few CAB members have embraced the role of community advocates and whilst they feel free to question the purpose of research they tend to do this from a position of support rather than a position of neutrality.

The value that CAB members attribute to their association with KEMRI-CDC, and the way they position themselves as those who travel across the notional boundary between the community and KEMRI/CDC, is reminiscent of patron-client or client-patron relations. Ideas of patronage or patrimonialism are inspired by Max Weber's distinction between systems based on impersonal rational bureaucracy bound by law, and family-like personal systems of redistribution to dependents (Reynolds Whyte et al., Forthcoming). In African societies the dominant form of political accountability is not rational universalistic bureaucratic rule, but personalistic patron-client ties (Chabal and Daloz, 1999). In patrimonial systems material resources both derive from and are converted into interdependencies among people. What



matters is 'having people' - patrons and clients - and nurturing connections, which provide access to opportunities and resources, and enable you to fulfil your obligations to your kin, clan tribe or ethnic group (Smith, 2003). Patron-client relations are essentially ways of structuring exchanges between unequal parties and they are characterised by expectations and obligations for both parties (Reynolds Whyte et al., Forthcoming). Let us return to the CAB to illustrate: KEMRI/CDC as the imagined patron expects CAB members to stand with them and obliges them to foster partnership between the research organisation and the local community. In return CAB members, as clients or associates, receive allowances, training, connections and access into a circuit of knowledge about research activities, peripheral job opportunities and other developments. Becoming part of KEMRI/CDC in turn means that CAB members assume certain patrimonial responsibilities, which involve trying to bring about an equitable redistribution of research benefits in their respective communities. The importance attributed to nurturing connections in patrimonial societies also sheds light on why CAB members are cautious about voicing critiques about research. Their hesitancy about assuming the role of community advocates is likely to be related to fears about severing potential opportunities for self and community development.

Nonetheless CAB members' input is clearly of value and has helped researchers to be more sensitive to contextual concerns when it comes to implementing vaccine trials. Their advice does not necessarily change the course of trials but it helps to bring community concerns to light and to address them. In relation to ethics therefore their role is more about preparing the ground although they themselves also talk about the importance of harmonizing local culture and beliefs of the community with ethics guidelines. Currently it would be fair to state that CABs help raise awareness of research, but do not necessarily stimulate objective or critical discussion about research. The place and importance of critical awareness in CE is however still up for debate and may require new models of CE in which community representatives' occupy a less divided or ambiguous position. What is evident is that the increase in research taking place in Karemo, and related CE including forming the CAB, has contributed to a change in the community's thinking about research. This will be illustrated in more depth in chapter 10. For now however it is fair to say that increasingly people are attracted to the benefits of research and the boundaries which control access to such benefit

## Chapter 9:

# Gatekeepers' Perspectives on Community Engagement

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*'...most of my people still have got faith in the administration, the chief and his team, whenever we tell them something they say that is the right thing [so as long as you support?] They trust, but when I say that it is bad they turn the world against you.'*

*Male Chief, CR 5*

## Introduction

In this chapter I present the perspectives of 'gatekeepers' from the government-appointed district administration and the elected county council on the way in which KEMRI/CDC engages with the local community. I refer to these people as 'gatekeepers' since they have formal power to grant or restrict access to particular locations<sup>8</sup>. Gatekeepers' perspectives are influenced by many factors. Accordingly I begin by providing some background information on their official positions and roles, their relationships with the citizenry and why they matter in terms of CE. I also outline how KEMRI/CDC engaged gatekeepers from Karemo during preparations for community-based research, in particular the RVT.

To illustrate gatekeepers' perspectives on CE I then draw on observations from my fieldwork, reports of meetings, and a series of interviews undertaken with the District Commissioner (DC), and a leader from the county council, 4 chiefs and 1 assistant chief. To reflect inherent differences between the roles of various gatekeepers I differentiate between the perspectives of senior officials and those of lower levels of administrative chiefs who interact more closely with the local community. The data used for this analysis were collected between October 2008 and December 2009, which was 2-3 years into the establishment of a community-based research programme in Karemo. At this stage several rounds of demographic surveillance had been completed, the RVT had reached its' recruitment target, Tuberculosis prevalence cohort studies had commenced and preparations for the MVT were underway.

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<sup>8</sup> These powers have been delegated to district administrators since colonial times.

## **Who are these Gatekeepers & Why do they Matter?**

According to Holloway and Wheeler (2002 p. 47) 'gatekeepers' represent those who have the power to grant or withhold access to the setting in which one wants to conduct research. For KEMRI/CDC these people comprise those who hold positions of leadership within the government administration, the political leadership and the ministries of public health and medical services. In this chapter I focus on the first two groups with specific reference to officials from the district administration and elected representatives from the county council. I will turn my attention to gatekeepers from the ministries of health in chapter 10.

### **District Administration**

At the time of my fieldwork the highest ranking official at district level within the national administration was the district commissioner (DC). The DC is appointed by the Kenyan president and directly accountable to the provincial commissioner. In turn the DC supervises district officers (DOs) who are in charge of district sub-divisions, chiefs who are responsible for locations within these divisions and assistant chiefs who represent sub-locations. Historically the district administration has been the main body responsible for ensuring that government policies are applied at district level and that law and order is upheld. Under the new constitution some of these responsibilities are being transferred to local authorities such as municipal and rural county councils. Hence in the future it will be difficult to differentiate between the roles of the district administration and the local authority. A core distinction which will remain, however is that administrative officers are permanent public service employees, whereas council officers (such as the mayor, chairman of the council and councillors) are elected for terms office under a political mandate. For the purpose of this thesis it is unnecessary to comprehend the intricacies of gatekeepers' official duties however it is important to understand why these officials matter when it comes to the implementation of research.

Senior district officials such as the DC and DOs hold judicial powers and are charged with coordinating government activities across a district. This includes overseeing the work of non-governmental organisations and research groups who contribute to local development. Representatives from such groups are required to inform the DC and relevant DOs of their

work plans and obtain their approval (this is usually a verbal approval following the written submission or oral communication of work plans). Historically this community entry function was the main role played by senior gatekeepers played in terms of research. Once their approval was obtained researchers tended to collaborate more closely with chiefs in the implementation of research. However under the coalition government formed in 2008 there has been a greater push to enhance accountability and improve communication between the district administration, the ministries of health and other organisations working in the district. As a part of this drive a quarterly health stakeholders' meeting chaired by the DC and run in partnership with district health officials has been instigated. Any health-related organisations are required to attend this forum and provide detailed updates on their work.

As suggested above chiefs have historically played a crucial role in the implementation of research programmes. Chiefs are the face of the government at community level and are delegated certain legal authorities by the state which enable them to enforce the law, settle disputes and administer government policies. In addition - and in contrast to the DC and the Dos - chiefs originate from the communities they administer; hence they have strong family and clan connections. They are well known and command the respect needed in order to settle disputes and mobilise community members to attend barazas and other government activities. In essence they are intermediaries between the state and the people and their authority and judgement carries considerable weight on the ground. This is one of the main reasons why so much emphasis is placed by researchers on the involvement of chiefs in the implementation of community-based research.

The position of 'chief' was first instituted by the British during their colonial rule of African territories (Lonsdale, 1964). In order to save costs and to benefit from the perceived authority of indigenous leaders British colonial administrators created a system of indirect rule. They appointed Africans as local agents of colonial rule and delegated to them responsibility for translating orders, collecting tax revenues and enforcing law. This imposed chieftainship did not however generally reflect inherent leadership structures and colonialists tended to create artificial territorial boundaries. According to Berry (1992) colonial administrators failed to recognise that African societies were not divided into neatly bounded, mutually exclusive, stable cultural and political systems, but were instead

dynamic, changing communities, whose boundaries were fluid and ambiguous and whose members were often engaged in multiple contests for power and resources. This meant that community responses to externally appointed chiefs could be ambiguous and chiefs had to exercise strong leadership in order to discharge their duties.

Over time the chief became an established part of the Kenyan government administration and chiefs continued in office even after independence from colonial rule in 1963. Chiefs today are state functionaries who wear uniforms which resemble those of soldiers and whose main purpose is to apply government policy down the chain at community level.



**Photo 14: Administrative Chiefs in their Official Uniforms**

Their charter of service (Appendix II, Doc. 7) cites the following duties: To enforce the law; to prevent, manage and resolve social, political and other conflicts; to operate community policing; to enable harmonious co-existence of communities; and to hold interactive public barazas (open community meetings). As suggested above their work is primarily about applying government processes down the chain of command, and whilst their charter requires them to interact with and obtain feedback from the populace emphasis is placed on achieving cooperation. Hence chiefs tend to focus on communicating down the chain of

command rather than relaying community opinions to their superiors. This is of relevance to chief's involvement in CE in health research. When examining chiefs' current involvement it is also important to consider their past involvement. Graboyes (2010) provides some insights into this in her review of historical sources and oral accounts about the practice of medical research in East Africa in the 1950s. She describes how colonial medical researchers used chiefs to spread news about research, which was frequently misrepresented as treatment rather than research. With government support researchers expected the chief to explain the research to his people, overcome suspicion and achieve cooperation. Minimal guidance was provided on how chiefs should achieve these aims by researchers, who tended to turn a blind eye to any tricky tactics. For example, Graboyes (2010) cites evidence that chiefs ordered people to take part in research and issued fines to those unwilling to participate. Whilst chiefs do not exact the same level of authority in CE today it is important to be aware of this history in since people do not forget the past which can continue to shape current perceptions and responses to biomedical research in subtle ways.

### **Elected Representatives**

Over the course of my fieldwork relationships between researchers and elected leaders from the county council gained more momentum. In part this closer engagement occurred in tandem with the increased status and powers attributed to local authorities under the new constitution. In part it was also just a result of the growth of KEMRI/CDC activities at community level. Traditionally county council leaders and councillors, who represent different wards at community level, have interacted minimally with researchers. In fact, as discussed in chapter 6, researchers have been hesitant about involving politicians (i.e. elected representatives) in their activities. They are wary of their motivations and do not want community members to be unduly influenced by those who hold significant influence over public opinion. The fact that some politicians from neighbouring areas spoke out against research during a period of negative media coverage in 2004 (see chapter 3) served to increase researchers' reticence to engage this group (Big Issue Team, 2004). In addition and possibly more significantly the scope of the role played by councillors at district level has been unclear, and their terms of office transient. However as described in the next

section representatives of the local authority have begun to demand closer collaboration with KEMRI/CDC. Researchers have started to respond to this request in order both to increase understanding of the goals of their programme and to minimise any negative repercussions which could ensue from the non-involvement of political gatekeepers.

It is clear even from this short review that gatekeepers play diverse roles in terms of CE depending on their position and influence. There are those who provide official approval and those whose support is indispensable when it comes to rolling out programmes at community level. It is also evident that involving gatekeepers is not just about facilitating entrance but more importantly about retaining support over time. The range of gatekeepers has also evolved with KEMRI/CDC now being required to collaborate with a broader spectrum of community leaders including those who hold political office.

### **The Involvement of Gatekeepers in Community-based Research**

When the decision was made to extend the health and demographic surveillance system (HDSS) into Karemo division in 2006 senior representatives from KEMRI/CDC met with the then DC from Siaya District to discuss and agree on these plans. With his approval subsequent meetings were held with the DO and chiefs from this division. At these meetings the purpose of the HDSS was presented and possible benefits and disadvantages outlined. The chiefs and the DO voiced their support for the planned programme and helped raised awareness at community level. The chiefs were particularly active in mobilising community members to attend barazas where they could learn more about the HDSS from a team from KEMRI/CDC. They were also involved in helping researchers to recruit VRs to assist in surveillance activities.

During preparations for the RVT chiefs and the DO from Karemo were invited to attend an 'Educational Seminar on Clinical Trials, Rotavirus, Immunization and other causes of Diarrhoea' held in seminar rooms at a hotel in Siaya. This seminar was led by the study coordinator, project manager and community liaison lead for the RVT. Chiefs were given an overview of the trial protocol and asked to comment on ways to inform and engage the community about the proposed research. As part of this consultation chiefs were also asked

to organise a series of barazas at which researchers could discuss the trial with community members. This pattern of community interaction is KEMRI/CDC's primary strategy for disseminating information and responding to questions about research at community level.

To further strengthen relationships with chiefs KEMRI/CDC has instituted an annual chiefs' day at the field station near Kisumu. The aim of this event is to orientate chiefs to the broader research portfolio and provide them with the opportunity to meet senior investigators and visit research facilities and laboratories. It is also hoped that as a result of these days and other interactions chiefs will assume the role of ambassadors for KEMRI/CDC.

*'...we have this annual chiefs' day here at the campus...we would like them to sort of be our ambassadors out there so that when they go and meet someone who is a bit worried about us taking some blood samples, then they can clarify for them exactly what we use it for...'*

*CT Member, RS 06*

The following social situation describes one of these days which occurred during the course of my fieldwork.

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### **Social Situation: 4<sup>th</sup> Annual Chiefs' Day**

The 4<sup>th</sup> annual chiefs' day was held in July 2009 and attended by over 200 chiefs and assistant chiefs. The chiefs travelled to the field station by public transport and were given special permission to pass the 2 security gates which guard access to the KEMRI/CDC offices. They had to provide identification and their names were verified and checked off from a list compiled by clerical staff at KEMRI/CDC. On arrival attendees were welcomed with tea and donuts and given the opportunity to peruse information stands set up by different research branches within KEMRI/CDC. *'People of high calibre are gathered'* prayed one of the chiefs at the opening of the formal programme thereby affirming their position and conveying their honour at being invited to this event. The acting KEMRI Director welcomed them warm-heartedly to an environment where science takes place and where KEMRI collaborates with a wide range of groups including CDC. He explained that KEMRI's mandate is to look for ways of improving health and whilst this used to be all about doing research 'on' communities, it is now about doing research 'with' communities. He sought confirmation from the audience who responded with an animated: 'Yes'.

Following on the CDC Director announced the recent launch of the MVT describing it as a momentous occasion which may mean that your children or your children's children will not



experience or know malaria in the same way as you do. She declared that KEMRI/CDC is at the cutting edge of scientific discovery and stressed chiefs' and their communities' contribution to this by citing the employment of 200 people from the local community over the past year. Throughout the CDC Director's presentation and interactions she employed a variety of metaphors to communicate a central idea about the role of chiefs with regards to the research programme: Chiefs are the *'eyes of the community'*, *'our windows'* and *'the people who tell us what is going right or wrong'*. She encouraged constructive criticism and urged chiefs to keep KEMRI/CDC informed about community concerns and questions.

Both directors' presentations were followed by short contributions from Kenyan research branch scientists and a question time. According to the training officer a shift in the subject of questions was apparent, from an emphasis on employment issues to an interest in science and health-related action and policy. He commended the chief's for this and pronounced that this was *'the best chiefs' day so far'*. To conclude the formal programme one of the chiefs offered a vote of thanks. He said that *'down there when you mention KEMRI/CDC death is being, chased away and if you mention it 10 times a day you get more life'*. He then rallied all of the participants to join hands and chant quoting the US President Obama, who is of Kenyan patrilineage: *'Together we can'* (Photo 15).



After lunch chiefs from the same areas gathered together and were reimbursed for their travel expenses by the community liaison officer (CLO) and his assistants. They were also presented with a 'Partnership Award' (Photo 16) by KEMRI/CDC personnel working in their areas of jurisdiction. Finally photos were taken before the chiefs embarked on their return journeys.



Annual chiefs' days are unique in the way they open up a space which is not usually accessible to members of the general public or community leadership. Chiefs are welcomed in cordially, interact directly with senior researchers, and are exposed to the materiality of research i.e. the modern buildings, the well-equipped laboratories and the well-maintained landscape. Friendship is extended in the sharing of food and drink and gratitude expressed in formal presentations by researchers. The chiefs enjoy the pleasure of being 'in' which underscores their desire to be involved with a powerful organisation. The analysis presented in this chapter and elsewhere in the thesis indicates that strong emotions such as, desire, fear and anger can characterise encounters and non-encounters with KEMRI/CDC. In the above social situation the recognition afforded to chiefs heightens their desire to represent a modern project 'down there'. In contrast later in this chapter anger about non-involvement is expressed by senior gatekeepers, and chiefs relate common community fears about the research programme. In chapter 10 fear emerges differently when parents express anxiety about the consequences of no longer 'being with CDC' when the RVT ends.

At the end of the aforementioned annual chiefs' day the CDC Director informed attendees about plans to alternate the target audience for such events in future. The chiefs' day would take place every other year from now on with a biennial day for members of the district administration and elected representatives occurring in the intervening year. Although the Director did not expand on the reasons for this, these will become self-evident in the following section. The chiefs did not react especially to this announcement and those with whom I had closer contact were aware of senior gatekeepers' desire for closer involvement with KEMRI/CDC.

## **The Perspectives of Senior Gatekeepers at District Level**

To present the perspectives of senior gatekeepers I draw on interviews with the DC and the chairman of the county council and observations of events which involved them and other appointed or elected leaders. To set the scene I start by providing a resumé of a meeting which took place between the DC and senior representatives from KEMRI/CDC. The substance and circumstances of this meeting are critical to understanding key issues which shape the perspectives of senior gatekeepers.

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### **Social Situation: A Meeting called by the District Commissioner**

On Monday 27<sup>th</sup> October 2008 I was invited to join an impromptu meeting with the Siaya DC. The meeting had been called in response to complaints about the KEMRI/CDC research programme voiced during a district health stakeholders' forum the previous week. The KEMRI/CDC community liaison officer (CLO) had attempted to address grievances at the forum but the DC requested follow up in person with KEMRI/CDC directors and those who were leading research studies in Siaya. Recognising the urgency of this request the KEMRI/CDC leadership immediately dispatched a team of 12 (13 including myself) in 4 cars to meet with the DC in his offices at the District Headquarters in Siaya town. The team included a senior representative from KEMRI Centre for Global Health Research (CGHR), the CDC Director, the head of the HDSS, the CLO, the communications officer, a research doctor based at Siaya District Hospital (SDH), the coordinator for the Global Aids Programme (which supports district HIV care and treatment services), the study coordinators for the MVT and the Tuberculosis adolescent cohort study, a representative from the enteric research group, the HDSS special projects officer and the person responsible for community liaison in the RVT and MVT. I travelled in the same vehicle as some of the team and the tone and content of conversation conveyed the anxiety felt about potential repercussions. The head of the HDSS commented that it was well within the DC's jurisdiction to either close or hamper the KEMRI/CDC research programme.

On arrival at the headquarters the team was admitted into the DC's office fairly quickly although it was clear that both the DC and his secretary were taken aback by the size of the delegation. The DC complained that there were too many people but still sent for more chairs to cater for everyone. We sat in chairs in a semi-circle around the DC's large desk with the CDC Director and the KEMRI CGHR representative to his right and left. Following introductions it was agreed that the main agenda was to discuss stakeholders' dissatisfaction about the way in which KEMRI/CDC was working on the ground and to consider how to move forward.

The DC started the discussion by drawing attention to a plaque which recorded the start date of his mandate as October 2007. He lamented the lack interaction between KEMRI/CDC and himself since he took up office and pointed out that prior to this meeting no one from KEMRI/CDC had even been to pay him a courtesy visit. From his perspective there was *'something missing in communication'*. Related to communication he elaborated that people expected more transparency and a greater level of participation in decision-making in the current political climate. The predominantly Luo local population felt that since they were now in government (following the formation of the coalition government under a power sharing agreement between the parties of Mwai Kibaki and Raila Odinga) they should have a greater say about what happens in their community. Local and district leaders wanted to know more about how KEMRI/CDC operates and the DC stated that now was the time to address this demand. At this point the CDC Director interjected to state that she was happy to do anything and outlined how KEMRI/CDC already interacts with stakeholders with particular emphasis on regular meetings with the District Health Management Team (DHMT). The DC responded by saying that this information was not reaching his offices and that he had heard that Ministry of Health staff feel there was something missing in the way KEMRI/CDC communicates. This perturbed the CDC director who stressed that both she and senior researchers meet frequently with the District Medical Officer (DMO), especially in the run up of a new trial, and that they always send a representative to DHMT meetings. The CLO in turn remarked that he had not been invited to recent administration meetings to which the DC replied he should just get in touch and take part.

The meeting then moved on to concerns raised by district officers about the lack of links between KEMRI/CDC and local universities. The DC urged those present to facilitate closer collaboration and commended a cotton growing project, run jointly by the Kenya Agricultural Research Institute with Moi University in Eldoret. This led to a discussion about 'zoning' which related to complaints about KEMRI/CDC's perceived reluctance to allow other organizations to operate in areas where they conduct research. The DC advised KEMRI/CDC to team up with a wider range of stakeholders in order to prevent further speculation. In relation to collaboration he expressed scepticism about concentrating activities at the level of sub-locations and questioned chiefs' capacity to address broader concerns. In his opinion researchers should work more closely with district officers who supervise chiefs and who had felt sidelined. He used the following phrase to stress the importance of extending involvement: *'...remember that those who are left out make noise but if you involve them they can help correct public perceptions'*.

When the DC started to talk about the need for more public forums at which misunderstandings about research could be aired those present were quick to update him on planned events, and the CDC Director invited him to KEMRI/CDC's first results dissemination meeting scheduled for November. The DC welcomed this invitation but also encouraged KEMRI/CDC to do more about sharing research findings at district and community level. The head of the HDSS agreed and acknowledged that the HDSS had

previously only supplied chiefs and not other district officials with copies of their annual report. The DC appreciated this response and went on to call for the department that handles the community to be strengthened and reiterated earlier points about developing partnerships and improving communication. Pointing out that one tends to see the same faces at barazas he stressed the need to use a wider range of forums and channels including vernacular radio stations and newspapers. He also thought it would be a good idea for KEMRI/CDC to distribute a community newsletter issued in Dholuo and English. The head of the HDSS picked up on the essence of the DC's argument and concurred that KEMRI/CDC needed a new communication strategy: 'yes' replied the DC, *'one which emphasises dialogue'*.

In the closing stages of the meeting the DC raised questions about KEMRI/CDC's mandate; he stated that there was a lot of confusion about this on the ground, with people tending to associate CDC with non-governmental and KEMRI with governmental activities. He called for these perceptions to be corrected and the nature and remit of KEMRI/CDC collaboration to be communicated clearly to everyone. In terms of the remit of operations he raised a concern that had been put to him about infrastructural development. He asked for KEMRI/CDC to invest in more permanent structures rather than just bringing in containers. The CDC director explained that US government funds cannot be used for buildings, which meant that they had to apply for other funds to restore existing structures or erect new buildings, as was the case of plans for a new centre at SDH. The DC thanked her for this clarification, and stated that this was exactly the type of information that should be shared at the newly instituted quarterly district health stakeholder meetings. He explained that the aim of these forums was to avoid replication and encourage transparency: *'in the past some organisations would run away with money, so we need to make sure that people are accountable'*.

The style of the exchange in this meeting was very formal to start off with and gradually lightened up as the KEMRI/CDC delegation acknowledged and responded to the DC's complaints and concerns. By the end of the meeting the DC summed up with some words of appreciation and counsel by saying: *'this is a good starting point...but remember if you work in isolation you will have people fighting against you'*.

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The circumstances and content of this meeting raises several questions and provide us with unique insights into officials' views of the KEMRI/CDC programme at a specific point in time. The DC had been appointed in October 2007 and although KEMRI/CDC had interacted with his predecessor there had been no formal exchange with him prior to this meeting. This omission added weight to criticisms voiced by other stakeholders and resulted in the DC requesting a formal meeting with senior representatives from KEMRI/CDC. KEMRI/CDC

acted without delay and sent a very large delegation which included the CDC Director and senior staff from different programmes. The quick response, size and nature of the delegation communicated several important points: first KEMRI/CDC's fear of possible repercussions; secondly their commitment to addressing complaints; and thirdly the magnitude and influence of the research organisation. Regarding the latter it is interesting to note how the DC maintained control of the meeting even though he was initially taken aback by the size of the delegation.

The DC's above-described critique of the KEMRI/CDC programme comprised 4 main arguments which emphasised the need for closer interaction and improved communication. First he argued that the recent change in the political environment had resulted in an increased demand for transparency and consultation at community level. Local residents wanted to have more say about programmes taking place in their communities. Secondly community leaders were also keen for international organisations to form connections with local universities and groups with similar interests. He described how other organisations felt excluded by KEMRI/CDC. He criticized the use of zoning tactics and encouraged closer collaboration with other health stakeholders. Thirdly the DC questioned KEMRI/CDC's primary focus on chiefs when it came to facilitating both community entrance and the ongoing implementation of research programmes. He argued for closer working relations with more senior officials and drew attention to the pitfalls of not involving them. Fourthly he made a strong case for increased accountability at district and community level by stressing both the need for improved communication with his office and more public forums to discuss and provide feedback on research. In the Kenyan context it is important to remember that these sorts of demands implicitly communicate an appeal for access to and the sharing of resources and fringe benefits.

This meeting led to some changes in how KEMRI/CDC approaches CE in Karemo division. Most significantly the CLO started to visit the DC on a monthly basis to provide him with regular updates on the research programmes. Care was also taken to involve the DC in special events such as the visit of a media team from the USA and a meeting between RVT investigators, sponsors and community representatives. Over time increasing emphasis was also placed on interacting more closely with leaders from the political fraternity and others who influence public opinion at community level. Several 'opinion leaders' meetings were

organised which were attended by local councillors, the Siaya mayor, the chairman of the county council, youth representatives and clerks from the local member of parliament's office. Whilst this broader application of CE served to improve community relations it also raised questions about the research agenda, its remit and application.

## **Central Themes**

Three central themes emerge from an analysis of interviews with the DC and the chair of the county council and related observations. I have labelled these themes as follows: 'Detachment and involvement', 'Questioning the agenda: Research as an affair for the poor', and 'Relationships and obligations'. Each is examined in turn below.

### **Detachment & Involvement**

*'...we just see KEMRI vehicles running up and down doing research.'*

*Male County Council Leader, CR 57*

This symbolic analogy was repeatedly used by interviewees and others in informal conversations to portray anger about feeling detached from the KEMRI/CDC programme. Interestingly the DC used this analogy both to argue for closer collaboration and to draw attention to changing relationships on the ground. At the meeting described above he complained that *'research should not be a matter of driving up & down and going back to office'* (CR, 31). Six months later he then recounted how one particular incident - a KEMRI/CDC vehicle stopping to help at the scene of a road traffic accident - had had a positive impact of people's perceptions of the research programme. The humane intervention of KEMRI/CDC staff travelling in this vehicle demonstrated attachment rather than detachment.

Detachment was viewed negatively by the DC and a leader of the council who both warned about possible repercussions of not involving local leaders and those higher up in the official hierarchy.

*'...because if they sideline the political leadership they might get it rough because we are mobilisers and with our support they can go a mile more than where they have gone but if*

*they don't work with us hand in hand then it might not help them much, but we had agreed in principle that they will be contacting us calling us in meetings, then we know what they are doing so that we also support them.'*

*Male County Council Leader, CR 57*

Both argued that the active involvement of leaders can help prepare communities for research and extend the ambit of the programme. Their underlying motivations for closer involvement differed slightly; for example the DC was engaged in postgraduate study in the field of community health. Therefore he was keen to help correct misperceptions about trials and promote the dissemination of accurate information. He also requested more feedback on research findings and how these would benefit the local community. Whilst elected representatives were also interested in both the short term and long terms benefits of research their main motivation lay elsewhere. They hoped that collaboration with KEMRI/CDC, or to quote a county council leader, '*becoming part and parcel of KEMRI/CDC*' (CR 57) would help secure support for community programmes.

Hence when the mayor and a leader from the county council were invited to the KEMRI/CDC offices they presented a proposal for a jigger control programme to the CDC Director. They also discussed other forms of support e.g. building matatu (bus) stop shelters which could be used to post health messages and raise awareness of KEMRI/CDC. These proposals indicated that community leaders are keen for KEMRI/CDC to extend their mandate and to offer other assistance apart from research. Indeed at the groundbreaking of the construction site for a new research centre at SDH, which was also going to house improved HIV care and support services, the DC thanked KEMRI/CDC for all the support they had given the community of late. He stressed that the community really appreciated the way that KEMRI/CDC was moving beyond their mandate of research. At the same event he also congratulated researchers for improving their communication strategy and urged '*that now we are linking up - let's keep it that way*' (CR, 31).





**Photo 17: Groundbreaking for new Clinical Research Centre at SDH, May 2009**

### **Questioning the Agenda: 'Research as an Affair for the Poor'**

*But may I ask why did KEMRI choose Kenya and particularly Siaya? I know for this vaccine trial (malaria vaccine trial) hmm why did they chose Siaya, because of the low population the lower 'nini' [I mean] the lower income, so that people would accept?*

*Male County Council Leader, CR 57*

Certain apprehensions and some scepticism about the KEMRI/CDC research programme became apparent in discussions with leaders from the political fraternity and during meetings with opinion leaders. For example the chairman of the county council expressed reservations about *'the research being done on children as opposed to when we were young they were done on either, either guinea pigs or done on rats'*. He also questioned researchers' motivation for undertaking trials in an area where economic deprivation was widespread. Equally he felt it was pitiable to conduct research in health facilities which were unable to provide patients with basic essentials such as bed nets to prevent malaria. With

these statements he asserted his authority and responsibility for speaking up when things are not done properly. His criticism about the lack of basic essentials of health facilities was directed both at government health officials and researchers. More importantly his observations raised critical questions regarding the ethics of conducting research in resource-limited settings.

The DC also commented on these dilemmas and explained how underlying poverty and the lack of government resources meant that *'people expect that KEMRI/CDC should give more support to these communities than what they are doing currently'* (CR 31). He reasoned that it was very difficult to apply a research agenda without attending to other pressing health issues. This observation was reiterated in opinion leaders' requests for help with other disease prevention programmes such as de-worming and jigger eradication, and their questions about the demarcation of space for research activities in busy health facilities. They argued that any space sectioned off for research within the paediatric ward at SDH should be made available to general patients when the ward was congested.

At the heart of these questions lie concerns about the equitable distribution of benefits both for those participating in trials and those hosting trials; how will trial participants benefit from the profits that manufacturing companies make from new vaccines, and how can we ensure that local communities prosper from the research enterprise in terms of employment, infrastructural development and commercial opportunities?

Both the chair of the council and the DC associated research participation with poverty. This view was also expressed by some fathers whom we interviewed separately in a sub study and substantiated by the experience of VRs based in urban areas.

*'I would believe these people, the vaccine trials you are doing on ordinary 'mwananchi' [ordinary citizen] child yeah ordinary 'mwananchi' [ordinary citizen] child you are not doing it on somebody like Onynago's child, I have been to the hospital I see these people going to villages in the villages in ordinary homes, and I will put a challenge to you, tell me which prominent home have you carried the research?'*

*Male County Council Leader, CR 57*

This quotation suggests that apart from the 'stigma of exploitation' (Big Issue Team, 2004) widely associated with research there is also an additional 'stigma' attached to taking part in research-namely that if you take part in research you must be poor. The quotation also

claims that researchers do not target those who are better off. In regards to the latter claim both the DC and a leader from the county council argued that KEMRI/CDC needed to engage with a broader section of society including those from the middle classes. They stressed that research should not be perceived as *'an affair for the poor'* (CR, 57) and that it was important to include children from wealthier backgrounds in order to achieve a more representative sample of the population. They also thought that middle class parents could serve as effective spokespersons to promote the work of KEMRI/CDC.

The 'stigma' attached to research participation is however not just a result of researchers targeting particular population groups over others. Those with financial means take pride in being able to pay for their children's health-care and are more sceptical about the possible outcomes of trials and researchers' motivations. These attitudes were communicated very clearly in the undertone of my interview with a leader from the county council. Whilst he advocated for more engagement with the middle classes he also remained doubtful about the research programme and in particular the involvement of children in trials.

### **Relationship & Obligation: Demonstrating Solidarity**

This theme is very closely linked to what I have presented above and relays explicit demands for solidarity in a partnership characterised by actual and perceived differences in access to resources. It also relates directly to discussions about patronage, expectation and obligation which were touched on in the summary of the previous chapter.

A week after the meeting between the DC and senior representatives from KEMRI/CDC described above I witnessed the following social situation which underscores how relationships and obligations are closely entwined. This social situation took place during a community meeting held at one of the health facilities hosting KEMRI/CDC trials. Kogelo Dispensary is located near the centre of a dispersed village within large grounds owned by the local community. At the time of the meeting a police station was also being erected within these grounds, co-financed by community fundraising and a local government grant.



**Photo18: Kogelo Health Dispensary**

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### **Social Situation: A Request for Support and Solidarity**

It was the 3<sup>rd</sup> of November a day before the 2008 US presidential election which would determine whether Barack Obama succeeded in becoming the first black American president. A large crowd was expected to assemble within the grounds of the health facility which was just 1km from Obama's ancestral home. The local community had planned a schedule of events to mark the occasion including prayer meetings, drama, dance, speeches and the overnight screening of the election results. Provincial and national dignitaries had been invited and journalists from across the world were beginning to arrive at Kogelo. The local community and Kenyans in general greatly anticipated the possible election of a black American president of Kenyan patrilineage.



**Photo 19:**  
**A man from Kogelo touching a portrait of Obama painted by a local artist**

To prepare for these events the DC, local chiefs, the Luo elder Riaga Ogol and his entourage, the Siaya mayor, the chairman of the county council and other political representatives, the police chief and other police officers, community leaders, health facility staff, community health workers and other community members had assembled for a public meeting. The KEMRI/CDC CLO and communications officer (CO) were also present in order to be available to speak to journalists about trials taking place at Kogelo. The main agenda for this public meeting which was held under a marquee decorated with Kenyan flags was to discuss the proposed schedule of events and confirm security arrangements.

As part of a broader discussion the DC referred to the need for KEMRI/CDC to strengthen linkages across the local community. He claimed that people were not sure what was going on and as an example he asked the chairman of the council what he knew. The chairman said that all he knew was that it had something to do with malaria and children. There was some laughter about this, but was clear that the DC was trying to drive home a particular point about the need for closer collaboration with senior officials. During the course of the DC's address he requested financial contributions to buy water and fuel for a generator. In between speeches from other dignitaries he called the CLO over to ask whether KEMRI/CDC could commit KSh 10, 000 towards the purchase of drinking water for attendees. The CLO

tried to contact the CDC Director but he could not reach her. Being put on the spot in this way the CLO found himself having to agree to this request since refusal would have undermined burgeoning relationships with the district administration. There was also something larger at hand here in regard to the connection between the local community and the US. This connection facilitated the acceptance of Kenyan/American research collaboration and helped to form a tangible attachment between research staff and local residents. For example Kenyan and American personnel visited President Barack Obama's grandmother regularly and in turn she opened new research facilities and cut the ribbon at the start of the Kisumu World AIDS Day Marathon.

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This social situation demonstrates clearly that relationships in this context carry with them certain obligations. In this instance solidarity was exacted in a very direct manner but obligations can also be communicated in a more subtle manner by both parties. As relationships develop between researchers and the community co-dependencies can evolve which can both facilitate and complicate partnerships particularly when it comes to negotiating expectations. In the above scenario the purchase of water for a political function could not be justified under budget restrictions; therefore senior researchers made personal donations in order to honour the promised contribution. This type of resort is however not sustainable, feasible or judicious when it comes to responding to other expectations for material help.

### **Subtle Differences between Senior Gatekeepers' Perspectives**

In the process of my analysis some differences in perspectives between the DC and a leader of the council and other elected representatives became apparent. Both groups related a similar experience of initial detachment however overall the DC was much more positive about the research programme. In contrast the county council leader maintained a more critical distance and his associates' primary concern was to ensure that KEMRI/CDC made a significant contribution to the local economy. This is evidence of the patrimonial system which undergirds the Kenyan political system. As a patron the county council leader was keen to facilitate and demand benefits for his electorate. He was sceptical about the long term benefits of vaccine research. By contrast, the DC believed these trials would make a

significant contribution to the wellbeing of mankind. Pertinent to these differences in perspectives are the nature of these gatekeepers roles and lines of accountability, and the fact that political leaders mainly originate from the local community whereas senior district administrators are posted to the area by the government. In terms of accountability the district administration represents the state while members of the political fraternity represent themselves as the voice of their constituents.

Where their views converged was regarding the importance of consultation and the involvement of leaders at every level of the district. Both the DC and the chair of the council also expressed concern about the association of participation in research with poverty and urged researchers to engage with a broader spectrum of society, including those who are better educated and more financially solvent.

In his interviews the DC talked a lot about the value of community consent in this context. He explained how economically and educationally disadvantaged people were reassured if recognised community leaders approved of research. Whilst he acknowledged the problems this could pose in terms of undue influence he balanced this against other advantages, such as promoting a broader public discussion about trials and gaining insights into local and cultural beliefs. He believed that the former supported comprehension of research procedures when it came to obtaining individual informed consent. The chair of the council was more concerned about broader ethical questions which arise when one conducts research in resource-limited settings. While the DC agreed that it was very difficult to apply an exclusive research mandate in these settings he also thought that KEMRI/CDC was beginning to extend the boundaries of its mandate. To exemplify he referred to the planned clinical research centre which would house improved HIV patient support services and intervention of KEMRI/CDC staff at the scene of a road traffic accident. From his perspective these demonstrations of *'attachment'* to the local community were fundamental to success of the research programme.

## The Perspectives of Chiefs

To present the perspectives of chiefs I draw on 5 interviews with chiefs from Karemo where I was based and observations of interactions during events which involved these and other chiefs. The chiefs whom I interviewed defined the term 'community' as a group of people living in a demarcated geographical area and associated 'CE' with community involvement and sharing of information. They believed that as many people as possible should know about the research programme in order to promote understanding and counter negative feedback. In terms of their involvement in CE chiefs described 3 overlapping aspects: facilitating community entrance; brokering community understanding; and negotiating community acceptance. They also associated involvement with KEMRI/CDC with opportunities for development. Hence I explore these factors in 4 interrelated sections.

### Facilitating Community Entrance

KEMRI/CDC is portrayed by chiefs as having followed due process when it presented their plans to extend the HDSS to Karemo in 2006/7. They met with the DC in office at that point and had a formal meeting with the DOs and chiefs during which they explained the aims, scope and potential benefits of the HDSS and future trials. Members of the administration were persuaded of the advantages and helped researchers to inform the broader community. They mobilized community members and organised barazas where researchers presented their plans. In interviews chiefs stressed the benefits of collaborating with KEMRI/CDC in terms of improvement to local health facilities, employment and training of local residents. As the research programme grew a common pattern of community entrance evolved: *'they called the chiefs to a workshop, they called the opinion leaders to the same, they had a big baraza and then we rolled it down to the sub-locations'* (Male Chief, CR, 42). Chiefs described their role as both authorizing and facilitating research. They argued that their support and approval were crucial since community members place a lot of faith in administrators and trust their judgement.

*'...you know people believe in administrators [right], yeah, anything coming, at least they want to get a hint from administrators'*

*Male Assistant Chief, CR 56*



Respect for the judgement and capacity of chiefs was evident in CAB members' appointment of chiefs as chairmen for the alternating CAB in Karemo. To what extent this respect is attributed to the office of chief rather than the person is open for debate, and I was party to conversations in which both negative and positive pronouncements were made about different chief's performances of their duties. Literature informed by similar research in Kenya also suggests that whilst community members respect the opinions of chiefs, they are keen to make autonomous individual or household decisions about participation in research (Molyneux et al., 2005b).

### **Brokering Community Understanding**

*'People were called and talked to and everything was just explained to them...'*

*Male Chief, CR 25*

As an extension to their role in facilitating community entrance chiefs assumed some responsibility for brokering understanding about the work of KEMRI/CDC at community level. They assembled people and talked to them about the purpose of the research programme. Public meetings such as chiefs' barazas were portrayed as ideal forums for presenting information about the KEMRI/CDC research programme. Barazas represent the main forum for the dissemination of information at community level. They are also the places where state policy is defined and where disputes between residents are settled. Essentially they are the place where the representatives of the state interact with 'civil society' to discuss state policy, consider how new projects are applied in their given community (or public sphere) and where concerns can be voiced publicly. The latter was considered particularly important in relation to discussing and addressing rumours about research openly.

*'Until your people (researchers) came out in public and attended chiefs barazas and assistant chiefs' barazas, talking with them (community members) telling them why the blood is being taken and even the quantity is when they now become feeling free.'*

*Male Chief, CR 42*

Brokering understanding is not a straightforward task and chiefs recounted how community members were initially very apprehensive about research activities.

*'At first you know some of them were afraid of this, it was not even easy to get them and talk to them, some even if we wanted to go and visit their homes, like now we are here, the time when they saw the VR going round to release this, some used to even lock their houses and disappear [they were scared?] eh (yes) they were scared they came on pole pole (little by little) after sensitization.'*

*Male Chief, CR 42*

According to chiefs community members' fears were fuelled by 'propaganda' spread by people with a political agenda. One chief was particularly adamant about this stating that those circulating rumours had no basis for their claims and were unwilling to defend them publicly (i.e. at barazas). In contrast chiefs were officials with an invested authority who had access to accurate information which they communicated openly.

*'...you know these people who propaganda, they are people who don't have a base, because the chief has got a base because he has got office if he goes there you get him. Whatever he tells people has got some weight, the assistant chief also has got a base because he has got place where if you go you get him there so either at a baraza if you attend so if you just say that we have some people are just trying to mislead people around saying one, two three and with us we went to a seminar on such a such day up to this day and here is the document saying that that one is being done like this and that, you see, and that person trying to mislead people, where is he? Let him just come and explain his also now here, you see, he doesn't come to the baraza, he doesn't have something to produce, we brought that one out, it is rumours.'*

*Male Chief, CR 17*

The above quotation communicates something about the use of official status to counteract rumours. This was also conveyed in phrases such as *'...people changed because we penetrated everywhere in this location to tell them the truth.'* These observations raise important questions about the appropriate use of state authority in CE and the impartiality of chiefs in regard to supporting a modernising project which could benefit their areas.

## Negotiating Community Acceptance

*'...the community must accept it before it is being started.'*

*Male Chief, CR 25*

Community acceptance of research was viewed by chiefs as essential to ensure that people who want to participate in trials feel free to do so. One chief argued that unless the majority agree about the value of research those who want to participate in trials are at risk of being disregarded or victimised by other community members. His stance conveys more of a consultative approach to negotiating acceptance in contrast to the zeal relayed at the end of the previous paragraph.

*'So the community must first of all accept it [mmm] and agree to participate [mmm] eeh (yes), [the whole community?] eeh (yes), because if you find, maybe the community have accepted then the few get interested, if the community accepted it, is when they participate [right]. Even if everybody don't participate, but the one participating is not disregarded [right], you know if the community reject it and then maybe few people now try to participate, they hate them [right] they will victimize them [they will give them a problem], so first of all the community must accept [mmm].'*

*Male Chief, CR 25*

To attain acceptance of research, this chief explained, that you must first convince the community. It is not enough for a chief to stake his support for the research – he must build consensus. He described how this involved chiefs and CAB members sitting down with community members to discuss the benefits and disadvantages of research. These discussions took place at church meetings, chiefs' barazas, village elders' meetings, anywhere where a group of people could be gathered. According to the chief his role was to bring a proposal to the table in a way which allowed everyone to voice their opinions freely. The public nature of this discussion and who said what clearly played a crucial role in terms of building consensus.

*'And then people will see if so and so is saying the research is good, I think this thing is good, and even if there is somebody who is against it, he will be afraid, he will be silent about it, because I know even now not everybody will be for the research, some people are against it, they cannot take their children there, but you know they are silent because most of our people were for it, [mmm, the majority support it?] the majority support it. So once the majority support this something, it will be easier to sail through.'*

*Male Chief, CR 25*

The quotation above describes how the opinions of certain people can shape general responses to research. Whilst the chief did not specifically state who these people were he had previously underlined the role of CAB members in achieving consensus about research.

### **Opportunity for Development**

*'They (community members) are still begging that the research is good, but they still need a lot of assistance'*

*Male Chief, CR 42*

Chiefs are responsible for overseeing development activities and it was evident that they viewed research as an opportunity to boost such activities in their locations. They also actively advocated for local community members not to be disadvantaged when it came to employment and training. To this end they persuaded KEMRI/CDC to erect notice boards at every chief's camp so that job advertisements could be displayed locally. In terms of development chiefs were keen for trials to be based in health facilities in their areas both because of short term infrastructural improvements and to increase the likelihood of benefitting from longer term research outcomes. They frequently requested KEMRI/CDC to extend to its programmes to other health facilities across their area so that more people could benefit. Overall KEMRI/CDC was viewed as filling gaps which were not adequately provided for by the government. As outlined below KEMRI/CDC's intervention was highly valued when it forestalled the need for community members to fund development projects.

*'Now even CDC, at the moment, our people is seeing it as a good body, because you see that maternity wing. That maternity wing was started by community members through harambee (community collection of funds), yeah, they built it up to, even doing roofing. Now they were left with plastering and putting doors, and windows and painting and the whatever. Now we went for the so called LATTIF (local government funds) [ok], we waited for money for more than four years, until we forgot about it. Now when the research CDC/KEMRI, that research of rotavirus came, they wanted at least a place where they can place their equipments and stationeries. They took that wing, the whole building, in fact it is the CDC/KEMRI that constructed that building up to the level you are seeing now, then they took some rooms. [They shared the building?] Yeah, so our people started having a feeling that in fact CDC has helped the community because after failing getting money from LATTIF, in fact we had a plan to go back to the members of the public [right] for the maternity wing to be completed. So in other words, CDC/KEMRI rescued us from involving members of the public.'*

*Male Assistant Chief, CR 56*

Apart from seeking to maximise potential community benefits arising from their collaboration with KEMRI/CDC chiefs also related how they had to mitigate community expectations. From the outset these expectations were high especially since CDC, as an international organisation, was considered to have access to considerable resources. Community members wanted to know '*...what CDC will actually do to them...are they going to build our school, are they going to provide us with food when we are hungry?*' Over time people became more used to the practice of research and instead of looking simply for broader benefits they started to question the inclusion criteria. They argued that all age groups, not just mothers and children, suffered from diseases like malaria; hence KEMRI/CDC should make more effort to include others in their programmes. As a result chiefs found themselves having to mitigate expectations whilst also advocating for KEMRI/CDC to extend its mandate and increase local benefits.

## **Discussion of the Main Themes**

This chapter relates a story of material engagements which have material implications. Senior gatekeepers in particular highlighted the complexity of applying a modern well-resourced project in an environment characterised by economic constraints. They challenged the research organisation to complement their research agenda with a mandate which pays increased attention to solidarity. They were concerned about the equitable distribution of research benefits and the widespread association of trial participation with poverty. Senior gatekeepers' perspectives communicate something about what Comaroff and Comaroff (1999, page 3) refer to as a neo-communal ethic which is characterised by civic or populist strivings for a moral *community* and *social* being at a time when a triumphal neo-liberalism calls into question the very existence of society and civic responsibility. Senior gatekeepers implied that partnership and collaboration between researchers and the local community must account for moral concerns, foster a sense of mutuality and result in concrete material contributions. Senior gatekeepers and local chiefs were ready and willing to contribute to this partnership on this basis.

*'Becoming part and parcel of KEMRI/CDC'* was presented as a way of benefitting gatekeepers' communities and augmenting their personal standing as senior officials, politicians and community leaders. Essentially senior administrators, elected representatives and chiefs alike communicated, albeit using different words and means, the aspiration to be associated with a powerful institution. Collaboration became more desirable for senior gatekeepers as the research programme grew and opportunities for learning, connections and material support became more evident. Whilst this suggests some imbalance in the basis of collaboration between KEMRI/CDC and senior gatekeepers, these officials also readily asserted their authority and stressed their indispensability in the application of the research programme. They demanded a constructive mutually beneficial partnership based on recognition and ongoing involvement of senior officials beyond initial approval processes. Senior gatekeepers' conception of collaboration in fact reflects their implicitly acknowledged patrimonial responsibilities which required them to nurture connections which provide access to opportunities and resources, and seek to fairly redistribute these resources fairly to their clients or people.

This chapter indicates that it is vital to pay due attention to state bodies in CE and to appreciate the civic commitment of gatekeepers in CE. Chiefs also stressed the public deference invested in the state, a respect for hierarchy that seems to override underlying questions about the state's capacity and reliability. State bodies are also increasingly demanding accountability and cooperation between government, non-government and international organisations. In regard to the KEMRI/CDC research programme this meant that senior officials did not only want to know about the rationale for research, they wanted more direct involvement in it and more transparency about material benefits. Accordingly increased interactions between researchers and senior gatekeepers, and concrete demonstrations of attachment and solidarity (e.g. trial staff stopping to help at the scene of accidents, funding for research and clinical infrastructures at SDH) led to the abating of residual hostilities. This resulted in a more positive discourse about the KEMRI/CDC at district level meetings and public functions.

The chiefs' story in this chapter differs significantly from that of other more senior gatekeepers. In part this is due to the closer attention played to this group by KEMRI/CDC historically. Their strategic dual position, as 'instruments of the state at community level' and people who wield significant kinship influence, has always been recognised. Effectively chiefs facilitate an interesting interplay between state, community and a modernist project. Chiefs' barazas provide spheres for civic discussion, participatory consensus-building and mediation about research related concerns. At the same time chiefs clearly do not represent disinterested parties in this process. They like their senior colleagues are keen for their areas to benefit from opportunities for development associated with research. This is not surprising in places where a lack of resources and related insecurity encourage opportunism. This opportunism is described by Johnson-Hanks (2006) as the fluid quest for possible connections which could lead to economic opportunity, exchange and mutual help, or ties to a responsive patron.

Chiefs also enjoy the sense of being 'in' with a modernist and powerful organisation. Whilst this serves to facilitate research it also raises questions about how to balance the notion and consequences of 'being in' with a healthy critical distance in CE. Overall chiefs associate CE with sharing information, brokering understanding, mediating acceptance and promoting development. Senior gatekeepers expect more and this needs to be appreciated. My analysis suggests that researchers need to be willing to engage materially and work more closely with gatekeepers to address overriding moral questions of social justice.

### **Synthesis of VRs', CAB Members' & Gatekeepers' Perspectives**

This chapter brings to a close the examination of community intermediaries' and community leaders' experiences and perspectives on CE. Hence it is an opportune moment to consider the similarities and differences which emerge from chapters 6, 7 and 8.

It is immediately apparent that these groups share certain desires in common even if they communicate these differently. Essentially all of them want to be connected with KEMRI/CDC and expect personal opportunities and community assistance to ensue from this association. Patrimonial responsibilities add weight to their need to gain access to a

powerful organisation and work for the distribution of material and social benefits to their kin, communities and electorate. Both VRs and senior gatekeepers expressed anger when they felt disconnected from KEMRI/CDC and emphasised the need for KEMRI/CDC to demonstrate attachment at community level. Senior gatekeepers also warned researchers against working in isolation and encouraged them to foster partnerships with local government bodies, academic institutes and other organisations working in the same area.

CE was viewed as having material implications by gatekeepers. Senior gatekeepers argued that one cannot apply a research agenda without accounting for inadequate health services and the poverty of most trial participants. For them the material expression of solidarity was central to CE and provided the basis for ongoing collaboration. They believed that the KEMRI/CDC mandate should be broader than merely research in the given socio-economic context. Chiefs also voiced similar opinions but in a much more subtle manner which was characterised by collaboration and opportunism. They simply wanted to ensure that their areas of jurisdiction were in the best possible place to reap the benefits of a modernising project. For VRs, CE also had material implications which were experienced in a more direct and personal manner; their connections with KEMRI/CDC meant that they had to negotiate and occasionally respond to villagers' expectations for material assistance.

The bases of the partnership between researchers VRs, CAB members and gatekeepers differ significantly. VRs and CAB members are much more closely aligned to KEMRI/CDC. In fact one could argue that although VRs represent and are nominated by fellow villagers they are answerable to researchers. CAB members are on paper more independent. However in practice they have assumed the role of patrons rather than advocates. In this context it is also important to remember the terms 'volunteer' and 'partnership' can deflect from the hierarchy and dependency which can underlie relationships, particularly relationships which are characterised by differential access to knowledge and resources. Senior gatekeepers in this respect are more equal with researchers and are keen to assert the authority that they can wield in terms of providing approval for research.

Although there are evident differences in the roles played by different community intermediaries and leaders in CE, the questions which arise from their involvement are similar. Those questions concern the more problematic aspects of relational ethics and



maintaining critical distance between community leaders, intermediaries and researchers. Where trust is employed as a means of mediation there is more potential for undue influence and where patrimonial responsibility undergirds the desire for connections community intermediaries are less likely to act as community advocates and community leaders may be less able to hold researchers accountable. These points have serious implications for the practice of CE and its association with improving ethical practice in research.

## Chapter 10:

### Diverse & Changing Community Responses to Vaccine Trials

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*'Now different people have different opinion, like with those staying in rural areas, they were just saying that these white people and these people that are talking in English, we don't know them, we don't know where they came from. They just come here and suck our blood, we don't know them and we don't want to talk to them, the police they are saying that we are terrorists you see [ok]. The, the nurses who are supposed to help us health wise on health education are saying that these people are, are paid a lot of money and they still need some money from us. They don't want to pay us, it's like they are paid a lot of money and they don't want to help us, now different tribes, different people have different opinions.'*

**Female VR, CR 30**

*'Yeah people around here are quite positive, they are now used to research'.*

**Female CAB Member, CR 44**

#### Introduction

This chapter is to presents the many diverse and changing community responses to the vaccine trials. As we will see these responses were wide-ranging, reflecting people's fears and suspicions as well as their interest in the research programme and their growing aspirations and expectations about what KEMRI/CDC could achieve in their communities. In my analysis I differentiate between Initial concerns, some of which draw on latent cultural idioms, and those which Emerged as a result of closer interaction with the KEMRI/CDC research programme.

The data presented in this chapter came from a broad range of sources including interviews with VRs, CAB members, community liaison team members, FWs, community members and parents of RVT and MVT participants. The interviews with parents informed the bulk of my analysis with the other interviews providing additional insights. In addition to these

interviews I also contextualised my analysis by drawing on field notes of CE activities. Examples of such activities included talks given by the community liaison officer for the vaccine trials (CLVT) at public forums including chiefs' and assistant chiefs' barazas, women's group meetings, RVT participant meetings, HIV support group meetings and savings associations meetings. My research assistants and I participated in a large number of such events; for example, we observed 22 CE activities in the run-up to the launch of the MVT. We also accompanied parents during the trial consent and enrolment process and observed certain clinical procedures.

Concerns that arise during the course of biomedical research are often referred to as 'rumours' both in the literature and in practice. At KEMRI/CDC researchers and community intermediaries use the term 'rumour' to denote popular concerns which they believe do not accurately reflect the 'truth' of their actions or intentions. The term 'rumour' carries connotations of hearsay and gossip. But such synonymous use of the terms 'rumour' and 'concern' can be misleading since some concerns expressed by community members do not share the characteristics of hearsay or gossip. Examples include concerns voiced about potential and medically-recognised vaccine side-effects and questions raised about differentials in care-giving between research participants and routine clinic attendees or hospital in-patients. Arguably then a distinction ought to be made between 'rumours' and 'concerns' without simply dismissing popular interpretations of research. Whilst these may seem unfounded from a biomedical perspective they can convey subtle and important critiques about the practice of research particularly relating to questions of fairness and the equitable distribution of benefits.

Over time, and as a result of closer interactions with and observations of the KEMRI/CDC research programmes, initial community fears and suspicions subsided. People became more used to the trials and a relationship of trust was established between research staff and community members. Experience and familiarisation created space for dialogue and allowed community members to voice their expectations and concerns more openly. Variations in responses were however still apparent particularly amongst fathers and certain sections of the urban population.

This chapter is organised into five sections: the first looks at initial responses and refers mainly to the RVT; the second relates parents' experiences of their children's participation in the RVT; the third traces changes in community members' responses to the KEMRI/CDC research programme; the fourth explores questions of decision-making about children's trial participation; and the final section summarises the key themes and questions which arise from this chapter.

## **Initial Responses**

Initial responses to the RVT were diverse and depended very much on community members' perspective, background, profession, gender and experience. There were those who were interested and keen to find out what trial participation would involve; those who preferred to sit back and see what happened; those who were inherently suspicious about researchers' motivations; and those who felt excluded and expressed some hostility about the research programme.

In this review of initial responses it is important to state from the outset that, despite mixed reactions to the RVT, the research team managed to achieve its recruitment targets and completed the trial successfully. Many mothers were very keen to enrol their children in the RVT even if they harboured fears about the vaccine and study procedures involving the withdrawal of blood. Others were also interested but preferred to wait and see how the first participants fared before enrolling their children in the study. Many of these mothers signed up their children at a later stage, or regretted their missed opportunity to join the RVT.

At the same time researchers' motivations and reasons for conducting trials in Karemo were questioned by community members, in particular men and urban middle class residents. The provision of transport reimbursement and free treatment gave rise to speculations about hidden agendas, and rumours circulated about researchers' intentions to abduct trial participants.

*Why this research, what is happening, why should we take our children for Rotavirus and whatever, why do they want children....children have been having diarrhoea... why is this nini (thing) now coming up, why do we need the vaccine, where had they taken it from?*

*Female CAB member, CR 44*

*'Yeah, when, like in Rota, there was, I think transport reimbursement [mmm], so when some people heard about it, they say oh, why are these people [mmm], they treat us free of charge, they do things free of charge and again, they give us money, what is happening here, there must be a hidden agenda. Why do they give us money?'*

*Male VR, CR 32*

Such inherent distrust is not something which is restricted to research or even KEMRI/CDC. A general scepticism about the intentions of outsiders including government agencies, non-governmental organisations, missionaries and anyone who cannot demonstrate strong attachment to the local community is prevalent across Karemo division.

*'...and then they will ask you how come that every now and again the KEMRI is here, the World Vision is here, what is, what is their interest in our Karemo?'*

*Female CAB Member, CR 07*

In part this scepticism can be explained by the fact that this area, along with most of Nyanza Province, was politically marginalised, as the main seat of the opposition, from the time of independence until more recently. This meant that the population felt excluded from political processes and related developments. It also fuelled misapprehensions about governmental initiatives, such as vaccine campaigns, which were alleged to be ways of curbing reproduction and decreasing votes for the opposition. Following a change in government in 2008, which has resulted in greater political representation for the local population, people are now very keen to be involved in projects taking place in their communities. They do not respond favourably to non-involvement especially if they feel excluded from potential benefits. This was the case for health professionals cited in the quotation at the start of the chapter. It was also the case for fathers of trial participants who felt sidelined in the trial consent process and threatened by FWs coming to their homes to ask questions about their children or their livelihood.

Overall two main areas of concerns were initially relayed by community members about the KEMRI/CDC research programme, namely anxieties about the trial vaccine, and conjecture about the withdrawal and use of blood in trials.

### **Vaccine-Related Concerns**

*'The vaccine will, especially with boys, it will make them to be impotent [ok], yeah, then some of the kids will die before they reach year one [right], some of them will just be retarded so they had all these issues. Some of the kids will be taken to the US [at the end of the study?] at the end of the, I think no they didn't even say at the end of the study, like you enrol then after some time they will take those kids to the US. [Yeah, I heard that they were worried about the FWs coming on the motor bikes and picking the kids and going?]. Then those vehicles (KEMRI/CDC vehicles?), yes, they have red number plates, but much of the issues were just to do with blood and bad things about baby boys [that is interesting, why baby boys?], you see like in terms of like they won't grow to be really full men so I think that worried them a lot.'*

*Female CLVT, RS 11*

The above quotation reveals concerns relayed to community liaison personnel about the rotavirus vaccine. It is difficult to measure whether concerns were specific to this trial vaccine or reflected more general discomfort with any new vaccine intervention. Fewer concerns were, however, raised about the vaccines used in the MVT; although this could be explained by the disease burden that malaria represents at community level. Malaria is a recognised health problem which affects everyone whereas very few people had ever heard of rotavirus before the RVT trial started.

In general the mothers, fathers, guardians or other family members of participating infants expressed support for the Kenyan Expanded Immunisation Programme (KEPI). They confirmed verbally that their children had received all the routine vaccines offered in KEPI and few reported doubts or negative experiences.

Parents' main fear about the RVT was that their children may die or be harmed mentally or physically if they were given the trial vaccine. According to those who enrolled their children this was one of the main reasons why other parents did not do so. This type of fear was also

relayed in some of my interviews with researchers and community members. Parents and community members also harboured anxiety about whether the trial vaccine would affect recipients' fertility.

Aside from these fears associated with a new vaccine, an element of uncertainty about the nature of the rotavirus vaccine was evident. One mother of a participating child told me that some parents were not sure if their children were being given a vaccine or a medicine. In part this might have something to do with the translation of terms; in part this could also be explained by the fact that the rotavirus vaccine was an oral preparation. Infants were given several drops and as such it resembled both the Vitamin K drops and the polio vaccine given to children under the age of one as part of their routine healthcare.

*...in Luo it seems to have mixed many things so some people term it as medicine and some people term it as chanjo (vaccine in Swahili)...*

*(Mother of RP 07)*

The fact that the RVT and MVT took place in regular public health facilities mitigated some of the parents' vaccine-related concerns. The trial vaccines were given within a familiar context; a context more closely aligned to what Streefland (1999) would describe as 'routine vaccination' in contrast to 'campaign vaccination'. Research nurses also gave RVT participants their regular vaccines and sometimes helped the general nurses administer regular KEPI vaccines to non-participating infants. These factors are likely to have normalised the trial vaccination experience since 'routine vaccination' has historically been less subject to controversy.

Over the course of my fieldwork, two government-initiated vaccination campaigns took place in Karemo. The first was a tetanus vaccination campaign directed at women of child-bearing age and the second a measles vaccination campaign. I heard about the tetanus campaign from parents of RVT participants, community members and chiefs. Most of the RVT participants' mothers whom we interviewed had received the jab at vaccination posts. However some of the community members we spoke to had avoided it. For example an older mother told us she could not get there, it was too far away, however her daughter-in-law challenged her and said '*...no that was not the reason. You were more worried about*

*circulating talk' (CM 05). Rumour suggested that the tetanus vaccine was a type of 'family planning' that might even affect future children's fertility.*

*'Some people don't want to go like, you know some people say, why is the vaccine just given to ladies and women, why not men, so some people thought it was a family planning (laughter) and refused to go, yah. They don't understand why is just given to girls and women, why not men, yah. And with me, I just went. There was one I was given when I was also still in school,'*

*Mother of RP 02*

The district public health nurse reported that this measles vaccination which took place in August 2009 was much more successful than a campaign held in 2006. In 2006 considerable scepticism about governmental intentions had been expressed, so this time the campaign team worked hard at mobilising the population and involving key community stakeholders. Even so parents of MVT participants related how historic concerns about vaccines continued to deter some people.

*'Some are saying that they are for hurting the children; for example when we were going for measles vaccination, a mother said that these are government drugs that are meant to hurt children. So we asked her how it would hurt the children. She told us there was a time Moi government produced a vaccine and took it to Kikuyu land to make the male child impotent. So we told her that was her opinion and we would continue taking our children and if the government can do such a thing, then it is them who would lose. So we took our children and others refused.'*

*Mother of MP 04*

## **Blood Rumours**

The initial stages of the RVT were characterised by speculations about researchers' motives which were primarily communicated by the means of blood rumours. Blood rumours also emerged at the start of the MVT albeit to a lesser extent. This is of interest since the MVT participants were required to provide more blood samples than RVT participants. In fact apart from providing pin prick drops of blood for HIV testing only a sub-group of RVT participants had to provide venous blood samples. In the following paragraphs I explore the ways in which blood rumours emerged in the RVT and try to understand the underlying meaning of these rumours. I will not comment on the origin or history of these rumours



here as this is documented extensively in the literature to which I have referred in chapters 2 and 5 (Geissler, 2005, Geissler and Pool, 2006a, Fairhead et al., 2006b, White, 1993, White, 1995, White, 2000, Vaughn, 1991).

According to VRs conjecture about a surreptitious blood trade; '*ohangla remo*', which benefitting white researchers was widespread at community level during the RVT. Within this context of suspected exchanges of value, certain study procedures, such as travel reimbursement, home follow-up and the provision of free medication and treatment provoked concerns about hidden agendas.

*'...they said the study staff is transfusing blood from their kids and they collect it together, they sell them to the wazungu (the white man), at sometime they used to see wazungu who were working with the CDC, mmm, so they said ah, this a muzungu (white person) business'*

*Male VR, CR 32*

*'And he (a father speaking to the field supervisor) told me that since he has been young, there was no time when somebody came to remind him to take his kid to the hospital, I mean [ok] which hospital is this where you are reminded to take your kid to the hospital and you are paid 120 shillings, and they get blood? Something has to be going on...'*

*Male FW, RS 09*

*'Then also free medication was also a very strong rumour I remember yeah, why do you give free things yet we should be paying? So like you may think you are helping but you are causing more trouble, yeah, even the free medication was really an issue...all these benefits why? You must be having hidden agendas'*

*Female CLVT, RS 11*

People were not used to receiving benefits or being paid for going to the health centre and wondered why participants were being given money - '*it could only be for blood*'. Even amongst parents of participants travel reimbursement evoked varied interpretations with some viewing it not only as a payment for travel expenses, but also a payment for blood. Indeed the CLVT was told by parents of MVT participants that '*...the money they get for transport reimbursement is not enough it is not enough for the blood that is being taken...*' Similar sentiments were also expressed at barazas and relayed to research staff by VRs.

These responses suggest that questions about the fairness of the exchange between participants and researchers were being debated at community level. Such questions and sentiments were also communicated by the means of rumour and speculation.

*'Ok, rumours ok I can remember like the rumours like we would withdraw almost you know goro-goro is 2kg of blood (laughter) from the child that blood that they would withdraw is taken to the US they sell it and in the long run they gain and us we don't gain.'*

*Female CLVT, RS 11*

This excerpt describes a rumour which, if taken at face value, could just be written off as improbable and false. However, when examined more closely it communicates a significant underlying message about the equitable distribution of research benefits. This is an example of how rumour can serve as a tool or idiom for popular expression of scepticism.

Other fears about blood were also the subject of much discussion at community level, for example the amount of blood taken and its subsequent use. Rumours frequently exaggerated the volume of blood withdrawn from infants and parents of participants found it difficult to judge whether the amount taken was indeed excessive. Venepuncture was frequently experienced as a stressful and painful event, which only served to heighten anxieties and increase fears about potential negative repercussions.

*'People are, because being that you explain to them even three times, people believe that blood is very less in the body and being that it is taken and this blood is what the child is using [mmm], maybe even the way people are feeding with a lot of difficulty, sometimes the child only took porridge, still they are going to take blood, how will this affect my child, that is the fear they have, and also this disease of, they ask that perhaps they might be testing for HIV in hiding.'*

*Female VR, CR 39*

For researchers ascertaining participants' HIV status was a critical factor in evaluating the efficacy of the rotavirus vaccine. The investigators were seeking to establish whether the vaccine produced an adequate antibody response in HIV+ infants and whether it prevented rotavirus-related diarrhoea in this sub-group. Hence all participants, both infants and their mothers, were offered an HIV test as part of the trial. Mothers were informed about this during their first visit to the research clinic and were given the option to consent or withhold

consent for HIV testing. The consent process was viewed by researchers and community representatives (such as chiefs and the district commissioner) as an important opportunity to provide detailed information, discuss parental concerns and ensure that parents or guardians understood all aspects of both the trial and the HIV testing. A separate consent form was used to document their decisions regarding HIV testing. The importance attributed by researchers to elaborating on the purpose of HIV testing and obtaining participants' consent for this separately is underlined by the fears expressed in both in the quotations above and below.

*'Some people were saying that they were taking blood, maybe they are going to put, I don't know how they are going to put the virus (HIV) there and bring the result, the baby is positive. That's why some people decided not take part in the study.'*

*Mother of RP 02*

At the time of the RVT, HIV was still highly stigmatised at community level with conspiracies about its origin and transmission persisting in some places. In the interview excerpt above a mother talks about how some people conjectured that the researchers were intentionally infecting infant trial participants with HIV.

Contrasts were drawn by parents and community members between the use of blood in research and in routine health-care. Venepuncture as part of routine care was viewed as necessary to identify the cause of illness and people were reassured by the fact that they were given the results of their blood tests there and then. Venepuncture in research however raised suspicions since participants were not given the results straight away and blood was analysed at laboratories located away from the research site.

*'Eh (yes) what are they going to do with my blood, because in the hospital my blood is taken the test is done and then the result is there we finish. (But here they don't see that?) Eh (yes) for example you take my blood here you have to take it to the laboratory and then the results will be later, that is the difference that I think they see.'*

*Female VR, CR 29*

Even though the reasons for taking and shipping samples to other places for testing were outlined during the consent process, participants still tended to express unease about the use of blood in research. They suspected that additional tests (particularly those related to HIV) were being done without their knowledge. Some were also influenced by popular suspicions that drew links between the use of blood in research and its use in witchcraft. The latter mainly emerged because people were not sure about where the blood was being taken and what was being done with it. One mother told me that people from her village believed that researchers could use the blood in the 'wrong way' and cause the death of a child. This mother's child had actually passed away during the trial (although she did not attribute this death to witchcraft).

Blood rumours are very persistent in this setting and the fear of blood being taken can provoke emphatic expressions of resistance.

*'When we go to visit another home the mother told us that I don't want CDC/KEMRI near me because I live here, alone in the bush, I don't want people who will come in the night and slaughter me because I am alone, because I have heard that CDC/KEMRI are after the blood...'*

*Female VR, CR 29*

The community liaison officer (RS 01) explained this type of response by reflecting on the value of blood: *'...blood in our community is precious, it is considered as 'life'. If you spill somebody's blood, that's probably killing or just slashing somebody [harming them], that is an abomination, that's very, very serious because blood is associated with life, because normally people see that when you don't have blood, you die'*. Similarly a CAB member also stressed the value of blood with a particular emphasis on fear and how it can contribute to the persistence and intractability of rumours.

*'Yeah, the question that has really refused to go away is this issue of blood. I would say that in our culture people simply fear blood, yeah. In our culture, you don't just kill, people fear blood so even if somebody sees a little drop of blood (mmm) they feel that that should not happen.'*

*Female CAB Member, CR 02*

## Negotiating Rumours as a Parent of a Trial Participant

*'I know the benefits I don't listen to what people say.'*

*Mother of RP 02*

Here I explore how parents of trial participants negotiated rumours and negative 'talk' about the vaccine trials. Their primary response was to remember the benefits they experienced as part of the vaccine trials and ignore what people were saying. To explore parents' responses and related negotiations in more detail I describe, below, two social situations which occurred during the course of two families' involvement with the RVT.

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### **Social Situation 1: *'I had tasted the goodness of KEMRI in the past'***

One of the mothers I interviewed told me how when she first enrolled her baby into the RVT a close relative had tried to stop her. This relative had also enrolled her baby into the trial but subsequently the infant had passed away. The grieving mother blamed the trial for her baby's death and was therefore seeking to block her kin and change her mind about allowing her child to take part. My interviewee told me that she insisted that she wanted her baby to participate in the trial and did not let her relative put her off. She was also not worried about the rumour, which started circulating after her relative's child died. People were spreading fear about the trial by saying that *'CDC is killing children'*. The main reason my interviewee remained positive was the confidence she had in KEMRI. She understood that KEMRI was collaborating with CDC in this trial and she had benefitted from the help of KEMRI in the past. In 1998 one of her older children was very sick and it was KEMRI staff that had cured her child and prevented her from dying: *'I just went to the hospital and the KEMRI department are the people who assisted me when the child was already quiet as if she is dead'*. At that time KEMRI had been helping to improve the children's ward at Siaya District Hospital (SDH) and some of the KEMRI staff were based in the ward. They had helped her sick child even though she was not taking part in any research. The mother's decision to enrol her younger child in the RVT was a direct result of this experience: *'...I had tasted the goodness of KEMRI in the past'*.

This mother went on to tell me how the same relative who tried to put her off from enrolling her baby in the trial now comes running when she sees her coming from the hospital with drugs. She asks her to give her part of the dose given to her by KEMRI/CDC for one of her own children who is sick. Her relative has not necessarily changed her mind about the trial but she is keen to access and experience medical benefits, if only second-hand.

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### **Social Situation 2: *'They took care of her well... and used to visit me frequently'***

This case scenario draws on the experiences of seven family members from one homestead (a conglomeration of houses within one distinct compound which constitutes a household). This household included the head of the household who was the grandfather, his wife, married and unmarried sons, daughters, daughters-in-law and their children. The oldest daughter-in-law's first child had taken part in the RVT but had passed away during the trial. Despite this she still spoke favourably of the trial and in fact none of the family members I spoke to seemed to apportion any blame to the trial. The grandmother said: *'when KEMRI/CDC took her grandchild they took care of her well and when the kid was admitted in Siaya, when she used to go there, she would see they were trying to take care, and when the kid passed away they still came back to visit so she is ok with that.'* The mother of the deceased participant herself said: *'I have been with KEMRI/CDC and they used to visit me frequently and even if the kid is sick then when I took the kid to the hospital they used to treat the child for free, so that is why I have prayed for them to come again'.*

This family told me that people in their village were more sceptical about the trial and some even surmised that children died because KEMRI/CDC were doing bad things with the blood they collected: *'They use it in a wrong way, witchcraft or something, and that's why the kids die.'* Thus when their child died villagers *'didn't talk about research they were saying that the kid has been bewitched'*. In fact when the child was sick their neighbours had told the child's mother to take her to a traditional healer to have her treated for a condition called 'sihoho'. According to local legend 'sihoho' is associated with bewitching and

therefore it does not respond to western medicine, even though some of the symptoms include an extended abdomen, stomach pain and diarrhoea. There is a particular sound that is associated with 'sihoho' when one taps the abdomen. When the mother heard this noise she decided to take her baby to a traditional healer. This lady prayed over the baby and then made a cut into the infant's belly, sucked the surrounding skin, and removed some human hair, a fruit called *onunga* and some small meat bones from the baby's abdomen. When the mother saw this she believed that her baby had indeed been bewitched. After that the baby got well but then the problem returned. Since they thought that 'sihoho' sometimes comes with malaria the baby's family decided to take the child to the research clinic for malaria treatment. After the child had been examined at the clinic she was immediately referred to the children's ward at SDH. The KEMRI/CDC staff on the ward treated her baby but she did not recover and died in hospital.

The mother spoke very lucidly and openly about this experience and did not seem to hold any grudges against KEMRI/CDC for what had happened to her child. The experience had not turned her against research and both she and other family members spoke favourably about the home visits performed as part of the vaccine trials and the care given by KEMRI/CDC staff.

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The above social situations raise some important points and they share a common thread. In both cases the protagonists spoke favourably of research and in particular the care and the follow-up they had experienced. The mother in the first social situation cited a very significant event in her life which had left a lasting impression on her. The trust she had gained from the help extended to her by KEMRI in the past gave her the confidence to remain single-minded about her child's participation in the RVT. The family in the second case scenario found themselves overwhelmed by questions about the genesis of their child's sickness and suspicions about bewitching; so much so that they delayed going to the research facility. But they themselves never questioned whether the trial might have contributed to their misfortune. They retained a positive view of KEMRI/CDC and the mother of the deceased child told me that she would not hesitate to enrol other children in research. In contrast the relative whose child died in the first case scenario was reticent and

apportioned some blame for her misfortune to KEMRI/CDC. Notwithstanding that, however, she was still keen to access benefits of KEMRI/CDC care-giving, if only from a distance. These case scenarios helpfully demonstrate that people can have varied emotional responses both when they first encounter medical research and also when something negative occurs which is (rightly or wrongly) attributed to trial participation, by certain people. Peoples' responses are not always based on scientific reason; they can be influenced by a wide range of factors including personality, peer and family relationships and past experience.

### **Experiences of Trial Participation: *'Being with 'KEMRI/CDC'***

*"KEMRI/CDC takes children and takes care of them"  
Household Head of RP 11*

*"KEMRI/CDC always take good care of the children when they are sick, they give them proper attention and treat them properly, that's why I am always grateful for KEMRI/CDC... They diagnose the child properly, and know the exact disease or problem that is affecting the child."  
Grandmother of RP 09*

Parents and guardians of trial participants came to associate being *'under KEMRI/CDC'* with receiving *'proper medical care'*. For them this care constituted; accurate diagnoses, good medicines, close monitoring, active assistance, referral to specialists, and good communication between families and medical staff. They highly valued the art of care-giving and the technical expertise available in trials and contrasted this favourably with care offered by routine healthcare providers, e.g. governmental services. Treatment provided by KEMRI/CDC was described as efficient, *'people are treated faster and in an orderly fashion'* (MVT 01), attentive, *'the doctors were giving the children much attention'* (RVT 08), dedicated, *'they take effort to make sure the child will get well'*, thorough, *'they do the follow up properly and do not desert you'* (RP, 07), and respectful *'the relationship with the mothers was also good'* (RP, 08).



Parents' experience of care-giving resolved any lingering fears they may have harboured at the start of the RVT. When they spoke about the study they mainly remembered the good things and were fearful of returning to routine health services when the RVT concluded.

*...in Rota they take the child sickness into their hands and they treat the child properly and accordingly but when you go to the government side you find out that most children die in the line when they have just been taken to the hospital because they are not treated on time...*

*Mother of RP 09*

Of relevance here is the fact that the parents whom I interviewed remembered being told about the benefits of the RVT but did not remember much about the trial vaccine except that it would help prevent diarrhoea. They talked a lot about the care and the security the RVT offered and did not mention risks of side-effects related to the administration of a trial vaccine. When I probed about this some family members did have questions about the safety of the vaccine and how it was tested. However this area of concern was not conveyed unless I introduced the topic. So whilst parents were fearful about the vaccine at the start of the study their experience of participation seemed to erase these fears from their memories.

Differences in care-giving were also observed by others, notably parents whose children were receiving medical care in the same health facilities as trial participants.

*'I saw a difference there were wards that were for KEMRI/CDC, there you see they attend to the kids after every short time, they test the child and then the second person has reached they look at the kid, after every 30 minutes you see someone coming with the kids file asking questions that is very different from where we were the other side. If one person goes round in the morning at 9 and the other one will come at noon and the other at 3 in the night only but CDC they look at these people after every short time... Those who we were with this side said that they wish there kids were also in the study with the CDC, it could have been very good.'*

*Female CM, 07*

The ethical implications of these observed differences in care-giving will be explored in more detail in chapter 11. Here I would like to focus on the sentiment expressed in the last sentence, a sentiment which is also communicated in the following quotation.

*'Mmm, to me like now what is happening at the District Hospital here for example eeh, if a child has been attacked with malaria [mmm], you will find a mother praying in her heart that why don't the KEMRI/CDC take my child [mmm]. Why, because they, you see they now have the belief and it is true the way KEMRI/CDC is handling the patient is quite different from the Ministry of Health and that is sure, even me I have witnessed this one at the hospital [mmm]. So you find that now every expectant woman, every woman with a little child would always want just attention from the KEMRI/CDC [mmm] yeah.'*

*Male CAB Member, CR 06*

These quotations suggest that community members' responses to research shifted and that trial participation became more desirable. Mothers were keen for their children to benefit from the care provided by KEMRI/CDC. At the same time they worried about what would happen when the trial came to an end, or if their child was not eligible for participation.

### **Ending Trials: "The promise of the new"**

In the months leading up to the end of the RVT the CLVT organised several participant feedback meetings. Their purpose was to inform parents and guardians of participants about the end date of the RVT, to outline final arrangements, respond to outstanding questions or concerns and to extend a vote of thanks. The meetings took place in the grounds of the health facilities which had hosted the RVT and on average 60-80 people, mainly mothers, attended each gathering. One meeting took place in a church next to the health centre but the others were all held in the open air. Parents sat on benches or on the ground in a semi-circle facing the representatives from the RVT team. These representatives included FWs and clinical researchers based at the respective health facility, the CLVT and a senior member of the RVT team. Each meeting followed a similar agenda: introductions and vote of thanks, an overview of the final arrangements, a synopsis of new trials due to start, an open discussion, a final summary, refreshments and the provision of travel reimbursement for attendees.

The atmosphere at these meetings was animated and when given the floor parents stood up spontaneously to tell their stories. These stories were presented as testimonies of their

gratitude for the care and medical attention participants received during the trial. Occasionally stories included references to concerns or hostilities parents had overcome in order to take part but overall these testimonies were positive and celebratory in nature.

*'I was initially concerned about my child taking part in this trial. However with time, I realized that my child was receiving better care and the trial staff were concerned about the welfare of the child. I am therefore very thankful I would like to encourage my fellow parents to allow their children to participate in future research studies of this nature without fear of anything. For the aim of this people is to see that children grow up healthy.'*

*Comment by a father of a RVT participant at a feedback meeting*

Testimonies frequently culminated in requests for KEMRI/CDC to include RVT participants in any new trials: *'Can we get a gate pass into the next study?'* It was evident that parents were very concerned about what would happen once the study was over; how could they ensure that their children would continue to receive good health-care? Some were worried about the reception they would receive at routine health facilities and many were concerned about how they would pay for medicines and in-patient care.

*"We had become like family with staff working for this study and we were being given V.I.P treatment every time we brought our children for treatment. We now don't know what will happen to us when we have to take our children to the MOH doctors..."*

*Quote from parent of RVT participant during a meeting*

The RVT trial team had always gone the extra mile to make sure that participants received the medical care they required. In some instances they had even done more than the trial protocol stipulated. They accessed nutritional supplements for undernourished participants and took positive action when HIV+ participants defaulted from routine patient care and support services. A clinical office was placed in the patient support centre at the SDH which resulted in trial participants accessing essential care more quickly. In this way the researchers removed some of the obstacles parents can face when seeking to access health-care for their children. The dilemma for parents now was how to sustain access to good health-care.

For parents one obvious solution was to remain attached to the KEMRI/CDC programme. Hence they were keen to find out more about the new trials which were due to start. They asked about the selection criteria and wanted to know whether children who had taken part in the RVT could enrol. The CLVT stressed that this depended on their age, and whilst she would like them to continue to benefit from research she was also keen for parents to understand that they were under no obligation to enrol their children in another trial. Picking up on the aspirations of parents another member of the RVT team used a religious allegory to describe how the RVT had to go away but a helper(s) was coming. The new trials were likened to the Holy Spirit which was given to believers after Jesus had ascended to heaven. This promise of something new made it easier for researchers to negotiate dilemmas which emerged at the end of the RVT. The continuation of the research programme allowed KEMRI/CDC to demonstrate its ongoing commitment to improving health conditions in participants' communities.

### **Changing Responses to the KEMRI/CDC Research Programme**

Above I noted how community members' responses to research shifted due to their experience of care in the RVT. Trial participation became more desirable and community members' responses evolved as they started to interact more closely with KEMRI/CDC. Whilst some concerns resurfaced at particular time points (e.g. blood concerns at the start of the MVT) people's attention became increasingly drawn to the benefits of participation. Their experience of the RVT and later the MVT served to allay prior suspicions about KEMRI/CDC, and strengthened relationships and trust between research staff, participants and community members.

*'This change of heart, what brought it, was that when something is new not most people agree with it, unless they have seen how it works, but now that CDC has come and has worked in Karemo and those who were in the study have seen the benefits of being in the study, so those who refused get the sense and see that what they had refused was really good and so they have joined, because if a child has been taken in the study she is well treated and taken care of, so it encourages those who had refused that this was something that was good.'*

*Female VR, CR 29*

CAB members recounted how many of those who had spread rumours about KEMRI/CDC changed their views and enrolled their children in vaccine trials. CAB members credited this change in thinking to two main things: 1) the good they could see in the programme; and 2) the dissemination of information about the programme. Researchers, VRs and even parents of trial participants concurred, and the latter believed that KEMRI/CDC would have no difficulties in enrolling future vaccine trials participants. According to interviewees from all these groups community members had recognised that children who were enrolled in trials were well looked after and did not have to pay for their care. They had also noted that fears about potential harm which could result from trial participation were not realised. They saw that the programme was good and what they saw was confirmed by what they heard from respected leaders in their communities. Parents of participants also talked about how they came to accept trial procedures as normal practice and were no longer as fearful about venepuncture or the administration of new vaccines.

Whilst my interviewees concurred that community members had become more positive about research this did not mean that they were fully convinced. Indeed one CAB member (CR, 08) described her community as '50/50'. What she meant by this was that even though people in her community were beginning to appreciate KEMRI/CDC's work, they were still unsure about enrolling their children in trials. I will return to this point in the section on recruitment, consent and decision-making about trial participation below.

### **Responses to Preparations for the MVT**

Here I describe community responses to information shared by KEMRI/CDC at public forums like chiefs' barazas. Information was mainly communicated by means of oral presentations and occasionally backed up by written leaflets. Oral presentations were based on a slide print-out of a Power-Point presentation (Appendix II, Doc. 8) developed by the CLVT and the MVT study coordinator. The presentation was checked for accuracy by the principal investigator for the MVT. The print-out was used by the CLVT as a guide in terms of what she needed to cover in her oral presentations. In the early meetings she followed the script quite carefully but as she mastered the content she referred to the print-out less often and also encouraged greater interaction from the audience. The CLVT was fluent in Dholuo and

able to translate the content of the information linguistically and conceptually as she spoke (the print out was not translated). When a technical term did not exist in the local language she used words from Kiswahili or English, e.g. 'chanjo' (vaccine) or 'placebo', but apart from this community interactions were conducted in Dholuo.

When addressing public forums the CLVT would usually focus specifically on transmitting defined messages about the trial, and then open up the forum for discussion. Occasionally she would adopt a different approach whereby, instead of starting with the messages about the MVT, she asked those present what they knew about KEMRI/CDC. This was the case at a baraza which took place several weeks after the start of the MVT where she was told that KEMRI/CDC are *'the people who write on peoples' doors'*, *'the people who treat Malaria'*, and *'the people who take blood from children'*. These responses provide us with an indication about the level of understanding and experience present amongst the general public at that stage. The definitions were not all negative; they simply encapsulated what community members perceived to be the core aspects of KEMRI/CDC's work. To explore these issues further we documented all the questions which community members asked the CLVT during barazas and other meetings presentations. I list these questions under subject areas in Text Box 5.

My classification of questions reveals that community concerns had become more focused on questions of exclusion and benefits rather than fears about what research participation may involve. Whilst questions did arise about certain study procedures (in particular venepuncture) people were more interested in finding out how to access the trial. Older community members expressed misgivings about their exclusion from research programmes and others also wanted the benefits of research to extend beyond those directly participating. Earlier we saw that the practice of reimbursement was initially received with scepticism and fear of hidden agendas. Several years on people now were asking openly how much reimbursement would be given, and they even questioned whether it was sufficient in certain instances.

## **Text Box 5: Types of Questions Asked at Public Forums between Jan-Sept2009**

### **Benefits**

- Will everyone receive free health-care?
- If the child is big and not in the age-group and is sick with malaria can they also treat her?
- Sometimes you can find a mother has a child who is sick for some time, can they also help us?
- Can you also help the lives of adults as well?
- Children who will be born after the malaria study is finished, what will be done about them?

### **Accessing the trial/Issues relating to exclusion**

- What about children who are not in that age bracket?
- Why only 1800 children?
- Can a child of 2 years join the malaria vaccine trial?
- Can kids from Gem (neighbouring division to Karemo) take part?
- Only 4 stations (clinics where trial taking place) are identified and people are coming from far, how come Mulaha (local clinic closest to place where baraza is taking place) is not included?
- Why does KEMRI/CDC take only healthy babies and not sick ones for their studies?
- Why do we take only fat and healthy babies?
- What if you child had been in another study, can they still be enrolled?
- You only take younger children; do you take those above 10 years?
- Why the study is not considering all children below five years to be enrolled in the study yet there are medical campaigns for all children less than five years?
- Are children who participated in Rotavirus study having a chance to join the malaria study?
- Are you planning to conduct malaria research on adults because they are also affected by Malaria?
- Why are we doing research on children only and not on adults?
- What about the old their antibodies have also gone down how will they be helped?

### **Practical & Logistical Issues**

- When will the children be taken for the study?
- If the number exceeds 1800 of enrolment, what will they do?
- How many people know where the KEMRI/CDC offices are?
- Where else in Kenya is this study being conducted?
- When a child is in the study, will they still get the KEPI vaccines and where will this be given?
- If a child is sick with an illness apart from malaria, do they still treat the children?

### **Reimbursement**

- What amount will be given as reimbursement?
- How much is the reimbursement? Is it whether you come from far of near or is it a flat rate?
- If the child gets sick in the night and you don't have money, how will the reimbursement help?
- In case the baby is sick at night and treated at Ngiya HC, will they get a reimbursement?

### **Study Procedures**

- What is the time span for withdrawing blood 5 times in the study?
- What if one leaves after getting one dose only?
- If there is excessive fever swelling at the injection site what can be done?
- What site is the blood taken from?

### **Scientific Issues**

- Why is it that only female mosquitoes transmit malaria and not males?
- The people doing TB research can they also do Asthma research?
- Is there a way CDC can finish mosquitoes since malaria is a disease that disturbs a lot in the community?

From my broader observations of barazas it was apparent that attendees responded differently to information which had a direct impact on their livelihood. For example, people were more animated during presentations about a seed exchange programme than they were during the CLVT's talk about the MVT. They were interested in the MVT but it was aimed at young children and most of the attendees at that baraza were older and did not have eligible children. Their primary concerns were for programmes which could improve their lives and at that particular baraza, some complained that older members of the community were not given insecticide-treated bed nets by KEMRI/CDC.

There were also notable differences in responses to the trials as between rural and urban areas. This was apparent in higher enrolment rates in rural areas and in some of the attitudes communicated by those who would describe themselves as better off than 'ordinary citizens'. Preliminary findings from a sub-study involving fathers suggest that participation in trials is widely associated with poverty. However some of the material related to this is contradictory and requires a more in-depth analysis. For example, some fathers stated that parents who faced economic constraints were more likely to enrol their children in trials in order to reduce healthcare-related expenses. Similarly those with means did not want to be connected with research since it was perceived to be 'an affair for the poor'. Giving a different perspective on this question a father who was interviewed by one of my research assistants talked about how some parents were embarrassed to associate with researchers and take their children to the clinic.

*'No it's just something like inferiority complex of human being, being that you are poor you don't have even a good cloth to put on you can't mingle with these people like people of the research that most...like there is a lady who told me that she find it hard to be with CDC staffs is because ladies who come to do interviews; the was one who embarrassed her with the husband because she came in a three quarter trouser. And according to Alego customs, a lady should not put on a tight fitting trouser.'*

*Father of MVT Participant*

This quotation raises some important socio-economic and cultural considerations and reveals how dress can be a barrier in more ways than one. The questions of poverty, access to health-care and decision-making about participation in trials are poignant in the setting where I conducted my fieldwork. On the one hand there is the rural population, who have



become very positive about research; *'they were seeing it as their personal saviour'* (Male FW, RS 07). On the other hand there is a mainly urban group of people who go to private health facilities and do not find out about research which could benefit their children. The disengagement of urban residents, in particular those who may describe themselves as middle class, was discussed by researchers, but a solution was not found.

In this section we have seen how community members' focus shifted increasingly to the benefits of participation in research. Changes in community responses to research were also characterised by increased expectations for material assistance at community level. KEMRI/CDC, and in particular CDC, is seen to be a wealthy international organisation. Therefore community members called on CDC to work tirelessly in their communities. Discouraged by the state of government services and health facilities and encouraged by infrastructural improvements made by the KEMRI/CDC research programme community members started to believe that *'CDC are the ones to bring change in the community'* (Excerpt from a report by a CAB Member, April 2008).

## **Recruitment, Consent & Decision-making about Trial Participation**

Recruitment activities for the MVT overlapped with CE events aimed at increasing public awareness of the trial and included other more targeted activities which were mainly aimed at mothers with young children. The fact that recruitment and consent activities involved very few fathers had important consequences which are discussed later. Recruitment activities included the distribution of leaflets about the study to households by FWs, displaying posters about the trial (See pictures below) and village-based meetings for mothers run by the CLVT, which were organised by village elders. VRs were also asked to let people in their villages know about the trial and a Tuberculosis trial taking place in Karemo also referred potential participants to the MVT.



**Photos 20 & 21: Posters about the MVT on a shop next to the entrance of SDH**

Mothers who signed up their children for the trials told us that they found out about the MVT from their friends, neighbours, VRs, barazas, health facilities (in particular maternal child health (MCH) clinics); churches and from other groups to which they belonged. In Siaya town a lot of the mothers first heard about the MVT at the MCH clinic at SDH. Indeed this clinic was the main focus of initial recruitment activities. A few weeks before the start of the MVT the CLVT visited the MCH clinic and talked to several mothers about the trial. She took down the details of those interested in participating and contacted them with an appointment when the start date was confirmed. A FW was also delegated to approaching mothers at the MCH during the first months of the MVT.



**Photo 22 & 23: Maternal Child Health Clinic, SDH**

## The Consent Process

One of the first mothers to give consent for her child to participate in the MVT was approached at the MCH at SDH by the CLVT. She returned on the first day of the MVT and took part in a consent conversation with another mother which was facilitated by a clinical officer (CO) in the presence of the principal investigator and me. The CO established a good rapport with the mothers and proceeded to read the consent form, stopping intermittently to clarify certain aspects and check comprehension. The elder of the two mothers interjected questions from time to time but the younger mother, who was a single parent of 18 years of age, followed proceedings quietly. When I interviewed this mother at a later date she admitted that she had been very nervous about the process.

*'I was not comfortable because I didn't know what they are going to do next. For the first time somebody is telling you there is something new here which has just come....Then that one makes me to be worried, the first time for my child'*

*Mother of MP 01*

The consent process went very smoothly and, at the end of the conversation with both mothers, each completed a comprehension test on their own with a CO. The test was aimed at making sure that they had understood the key points of the MVT and what participation would involve. Where there were gaps in understanding the COs went over these points again. Despite this it was evident that this process had evoked fear in the mother I interviewed, a fear that was possibly exacerbated by the fact that she was amongst the first to consent for her child to participate in the MVT.

I also interviewed the other mother who took part in this first consent. Her perspective was slightly different. Whilst she too was also worried about being one of the first to participate she talked more about how her thinking evolved and changed during the course of the consent process.

*'For the first time when I met them in the hospital I got doctors hurrying up, they are arranging some of the things and I got this mother, Mama Martine, I started asking what are this for, are we the only people to be treated? She told me we don't know they have said the others are coming, we don't know if the others are coming and as time passes by*

*we were the only people sitting. Thereafter we were taken the two of us to the consenting room and when we had started to be explained about this some of the things I had seen at the back of my brain, this thing I am not going to do. As the doctor started explaining there are some of the things I was thinking of, and it made me not to decide even not to take part because they had told us the three injection they are random, they are not the same, after they had told us that they are not the same. Now I asked myself now what if my child will be given this one and my child fall sick and the other one given this and it succeeds?...But sometimes I look over myself and say that if the three injections they knew what they are doing, let me assume they knew what they are doing...Then as time goes by I have even said let the child be taken, he is in the hands of the people who are experts, I am not an expert and I came to comfort myself that everything that we have in this world is from God...'*

*Mother of MP 02*

In the MVT consent was initially only obtained from parents or guardians by clinical staff. However as the trial workload increased FWs were also delegated responsibility for consent. Most people were consented in groups of 2-12 and the consent form was mainly read by the FW or clinician. Occasionally he/she would also ask group members to read sections of the text and he/she stopped regularly to check comprehension or respond to questions. The types of questions asked related to study procedures such as randomisation and the different vaccines the child could be given during the trial. Parents and guardians asked lots of questions about the rabies, meningococcal and hepatitis vaccines and many also wanted to know more about these diseases. One mother who was consented on her own wanted to know how those already enrolled in the trial were faring, she was afraid about her child being one of the first to receive the new malaria vaccine candidate. Concerns were also expressed about blood tests; parents wanted to know how much blood would be taken, when it would be taken and why. They also wanted to know what would happen during home visits and what they should do if their child got ill. They were particularly concerned about accessing care at night, at week-ends or on public holidays. Some parents also wanted to know if their children could use other medicines while taking part in the MVT, and if they could access free care at other health facilities.

## Decision-making about Trial Participation

Consent represents an important part of parents' decision-making about their children's participation in trials. In most cases the consent process simply confirmed the parents' desire for their child to take part in a trial. Many mothers were *'keen to be with CDC'*, since this conferred a certain status and meant that their children would be eligible for free and more individualised care. Other parents approached consent with more questions and less certainty, as was the case for the younger mother quoted above. I also witnessed a consent discussion between a FW and a mother which was terminated when the FW recognised the mother's discomfort. This mother had been approached at the MCH clinic that morning and, whilst she had agreed to come and find out more about the MVT, her body language clearly betrayed her reluctance. The FW gave her the consent form to take home to give her more time to consider her decision.

What people knew about; had heard about, or had seen or experienced of the KEMRI/CDC programme played a significant role in their decision-making about trial participation.

*'I thought of joining the study because I had heard that they help people a lot. And that is why I decided to join'.*

*Mother of a RP 03*

*There is a neighbour of mine who went there and told me that malaria people are recruiting babies, and then I decided to go because they will help the life of my baby.*

*Mother of a MP 04*

The first mother cited here had not only heard that researchers helped people a lot she had also received help from KEMRI/CDC nurses during a difficult labour. She like many others had come to value the presence of researchers at their local health facility. Mothers in Karemo are very concerned about the health and well-being of their children, and are keen to access the best possible care for them. Those who were familiar with KEMRI/CDC's work appreciated the benefits of trial participation reimbursement for travel, free treatment for their child, readily available medication, home visits and potential protection against common diseases; - and were not hesitant about providing consent.

Conversely mothers who knew very little about KEMRI/CDC, or had only just found out about the MVT when frequenting a health facility for a different reason, were more hesitant. Indeed one could argue that being required to provide consent on the same day one finds out about a trial does not support properly considered decision-making. Researchers were sensitive to this and took care to ensure that all parents understood what participation would involve for their children. On the rare occasions when mothers requested more time to discuss their decisions with their spouses or other family members, researchers took care to give them a copy of the consent form to take home.

### **Disengagement of Fathers in Decision-making**

The absence of fathers during recruitment activities, the consent process and other study visits is a matter of concern. In part this disengagement of fathers can be explained by the division of labour at household level; in Luo society mothers are primarily responsible for the health and well-being of young children. This does not mean that fathers do not get involved. But it does mean that mothers assume leadership in this area. It is mothers who take children for health checks and mothers are also the primary decision-makers in the case of sickness. They may seek financial assistance from their husbands to cover medical fees. However they also access help from the household head, often the grandfather, and sometimes draw on personal funds, especially if they are involved in petty trade. This means that women are used to making decisions alone about their children's health.

Whilst men accept women's leadership in caring for young children they like to preserve their position and feel undermined and devalued if their wives do not consult them about important decisions. According to Luo customs children and their mothers belong to their fathers and husbands respectively. Hence when mothers withheld information from their husbands about their children's participation in the RVT this had serious repercussions. Instead of finding out about the RVT from their wives many fathers heard rumours about the trial when they met with other men to drink and discuss politics. Some men did not find out about the trial until a FW turned up at their homes to conduct routine follow-up visits. FWs generally assumed that the fathers were aware of the RVT and after introducing

themselves continued with their checks and questions. These types of incidents could result in FWs being chased away and participants being withdrawn from the studies. Men were generally more suspicious about the RVT, and did not like FWs coming to their homes to ask questions about their children or their livelihood (in the case of the HDSS). Male FWs in particular were perceived as a threat by some fathers, who were wary about how their wives would respond to these younger men who arrived on motorcycles or bicycles.

One of the main reasons why many mothers did not involve their husbands in decision-making about the enrolment of their children in the RVT was because they thought they might refuse. The following reflection from the CLVT touches on this and encapsulates well maternal anxieties regarding the novelty of the vaccine research programme.

*'But I think the main, main reason was that this is something new we don't know whether it will be good or bad so let's just give it a try silently, then maybe in the near future if we see it works well then we can easily share with the husband.'*

*Female CLVT, RS 11*

Mothers were also reluctant to tell their husbands about some of the benefits of participation, for example; travel reimbursement. They tended to keep quiet about this payment in case their husbands asked them to hand over the money. Mothers were keen to keep hold of this money to buy food for the family and more often they chose to walk home rather than pay for transport.

Not all mothers chose to exclude their husbands from decision-making and some were not able to involve them due to their husbands working away from home. In households where fathers were involved relations between family members and FWs were much more conducive and fathers were more positive.

*'Yeah, some of them whose, the mothers who went home and sought the consent of their husbands about the trials and the husbands accepted, [mmm], yeah. They are even easy to work with. Than the ones who started getting bits of information, yah, they would get information from their drinking places about blood would just get very crazy...'*

*Male Fieldworker, RS 09*

As a result of the paternal resistance to research experienced during the RVT researchers made a more concerted effort to reach men for the MVT. The chief in one area helped them to organise a special meeting with fathers and in other areas meetings were held with bicycle transporters. It became apparent however, particularly in the first meeting, that men were reluctant to voice negative concerns in these settings. They tended to dismiss concerns as rumours and said that it was all right for the researchers to continue with their programmes. Cycle transporters were also not very willing to be detained from their work. Hence these meetings were of limited effectiveness in terms of fostering paternal engagement. As a result researchers resorted to trying to involve fathers indirectly by encouraging mothers to talk to their husbands about the MVT.

Paternal disengagement clearly presents a significant challenge for researchers. In order to explore this theme further we conducted a sub-study in which we conducted additional interviews with fathers of trial participants and male community leaders. Aspects of this work are ongoing; however preliminary findings suggest that fathers have questions about underlying motives for conducting research in their communities. They perceive the balance of benefits to lie in favour of researchers and associate willingness to participate in research with lower economic status. Interviewees argued for a more active paternal role in decision-making about children's participation in research, and stated that researchers should meet fathers in their homes or places of work. Fathers of young children rarely attend traditional CE forums and mothers can be reluctant to share information with their husbands. Intra-household dynamics were viewed as influential in decision-making and fathers with children enrolled in the MVT described a consultative process involving both parents. Fear and uncertainty about vaccine side-effects, concerns about exchanging children's life for money and rumours about blood were some of the reasons for withdrawal reported by fathers.

## **Discussion of the Main Themes**

In this chapter we have seen how initial concerns about the vaccine trials abated over time both due to growing familiarity with the KEMRI/CDC research programme and awareness of



the material benefits of trial participation. Trial participants' experience of care-giving in the RVT and MVT resulted in a more positive view of vaccine research generally and raised community expectations. In a bid to negotiate the 'new' to their advantage community concerns started to focus more on exclusion rather than inclusion. Core questions emerged about the boundaries of care-giving in research and the distribution of benefits at community level. These questions and related expectations require KEMRI/CDC to consider its main purpose as a research organisation and explain the constraints which control resource distribution and research participation. They also require researchers to think carefully about how to address questions of equity and justice when conducting trials in resource-limited settings.

Although perhaps not to the extent one may have expected in view of the literature presented in chapter 2, it is evident that historic and contextual factors can influence community members' perceptions of immunization and vaccine research. Trust is fundamental and can be affected by the perceived purpose of vaccine interventions, the place and mode of vaccine delivery and the sources of information. Concerns were less apparent when there is confidence in those delivering a vaccine intervention, and where value is attributed to the associated care-giving. In terms of a vaccine trial these factors appear to override any pre-existing misapprehensions related to potential risks.

The blood rumours which circulated at the start of the RVT and resurfaced intermittently throughout the RVT and the MVT reveal important underlying questions about equity and reciprocity. To all intents and purposes trial participants and their families see themselves as entrusting researchers with a material gift which forges a social relationship of obligation. Researchers have to learn to negotiate these obligations and understand how they can affect perceptions of their work. Currently researchers tend not to address the underlying meaning of rumours in CE, which may explain why some rumours are so intractable. Mothers of trial participants in contrast understand the material nature of blood rumours and counter negative talk by emphasising the benefits of participation and recalling positive interactions with researchers. What is particularly interesting about the way in which mothers of trial participants negotiate rumour is that they do much of this work by themselves. What makes them so positive about participation is their actual direct

involvement in research, which is lacking when it comes to some fathers. This chapter has highlighted the importance of involving fathers more openly and actively in decision-making concerning their children's participation in vaccine trials. It suggests that there is a need to develop procedures which will increase transparency about research aims, support information exchange and dialogue, and foster more discussion between parents when it comes to consent.

## Chapter 11:

# Community Engagement in Public Health Facilities

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*Also in the ward, there is a, there are projects going on, they are under my roof (uhuh) which fall under CDC, there is Mal 55 [yeah] Malaria 55, and then there is the University of Mexico [ok] and also there is one which is starting soon [yeah] about Tuberculosis vaccines.*

***Hospital Nurse, CR34***

## Introduction

This chapter describes how differences in health-care provision are negotiated when transnational research is integrated into public health facilities. It traces challenges encountered in collaborative partnerships between researchers, health officials and health professionals, and provokes thinking about ethical questions which arise in the conduct of a paediatric MVT in a district hospital and peripheral rural health centres and dispensaries in Siaya District.

To discuss the challenges encountered I have combined insights from my ethnographic fieldwork with the practical experiences of investigators and their professional partners as shared with me during interviews and informal conversations. Participant observation of trial procedures, CE and collaborative processes was undertaken between October 2008 and December 2009. The experience of integrating research into public health facilities and related challenges and questions were further explored in 15 SSIs and 4 FGDs. SSIs involved 2 hospital nurses, 1 hospital doctor, 1 health centre administrator, 1 hospital medical superintendant and 10 researchers from KEMRI/CDC. The first FGD was held with 5 nurses from SDH, the second and third involved members of health facility committees from a health centre and a dispensary, and the fourth FGD was held with members of the District Health Management Committee. Many other people whom I interviewed throughout the course of my fieldwork commented on differences between the health-care provided within a trial and that provided to general patients admitted to government or non-governmental

facilities. These interviewees included district and county officials, CAB members and parents whose children had been admitted to the ward either as KEMRI/CDC trial participants or routine government patients.

From the data presented in this chapter it is evident that whilst collaborative partners were in principle committed to the integration of research in places where general routine care is being provided, boundaries between scientific practice and general care were drawn in order to facilitate practice. Two paradigms of care giving - 1) 'research' and 2) 'general care' - were contrasted in terms of therapeutic relationships, accountability structures, working cultures and access to resources. Collaborative agreements between the health facilities and KEMRI/CDC provided a formal framework but did not account for all challenges that arose within the spatial and social dynamic or in decision-making processes. The additional challenges related to differences of care giving, material inequalities and distinctions of health-care provision. In this chapter I argue for the public articulation of these challenges in order to ensure that problems of inequity are not transferred from the domain of collaborative operations to the domain of personal morality, but rather can be continuously negotiated with all partners to achieve better solutions.

To frame my core findings I start with a chapter specific review of pertinent literature which touches on questions of collaborative ethics, models of health research, the location of science and boundary work. Hence this chapter includes a theoretical overview, a description and analysis of my main findings and a summary of core themes and questions.

## **Review of Relevant Literature**

Recent debates about the ethics of research in developing countries have drawn attention to some of the difficulties of applying international ethics guidelines in diverse local contexts (1997, Marshall, 2007, Kleinman, 1999, Emanuel et al., 2004, Lurie and Wolfe, 1997). In response Emanuel et al (2004) devised an ethical framework for clinical research in developing countries which would provide unified and consistent guidance. This framework emphasises the importance of collaborative partnership in transnational research including it as one of eight ethical principles. The authors argue strongly that due consideration must

be paid to developing partnerships between researchers, health policy makers, and the community in the design and application of trials in developing countries. Indeed the explicit and detailed reference to collaboration in this framework sets it apart from a similar model devised for use in developed countries (Emanuel et al., 2004). The principle of collaborative partnership and related benchmarks are viewed as central to efforts to minimize the potential for exploitation in clinical research conducted in economically disadvantaged settings. Benatar & Singer (2000) similarly emphasise the need for international researchers to have some understanding of and be sensitive to the social, economic and political milieu that frames the context in which their research takes place. They support calls for alliances between research stakeholders and broader CE programmes and urge that conceptual progress needs to be matched in equal measure by translation in practice (Benatar and Singer, 2010). In their view this will help to advance solidarity across the globe and support progress by enhancing capabilities and social justice rather than sustaining dependency.

There is strong advocacy for the research undertaken in poor countries to be integrated into the public health-care systems and to contribute to improved health-care in the community where the trials are undertaken (Benatar and Singer, 2010, Emanuel et al., 2004). What is meant by 'integration' raises broader questions about where research takes place and who is involved in its execution. There are at least three different ways in which research can be integrated although the level and manner of integration differs between these models. For example one could argue that investigator-initiated trials run by government health staff in public health facilities are fully integrated. A health professional identifies a problem affecting practice and develops a research protocol to identify practical solutions. In this instance research findings are likely to be applied and translated into policy with minimal delay.

The other two ways involve the collaboration of external organisations with government health officials. In fact a research organisation may adopt different modes of integration for different types of study and even at different times in a single study. The main distinguishing factor is the extent to which research takes place within public health facilities and the level of daily interaction between research staff and health facility staff. Broadly speaking it is

possible to differentiate two different models, although overlaps can occur between these models in practice. In one model of integration research participants are recruited from clinics within public health facilities and attended to in buildings which are also accessible to routine patients. There may be some spaces which are restricted to research participants; however the research processes are visible to other patients, and researchers and government health staff have to collaborate closely in order to perform their separate duties. In practice research becomes another means of accessing care within a public health facility, and the facilities benefit from additional staff, resources and infrastructural improvements. Research staff and hospital staff interact on a daily basis and research participants receive care in places where routine hospital patients are also attended to. The collaboration with hospital staff and ministry of health officials facilitates the study and, depending on the intervention, may help to speed the translation of findings into policy and practice. The MVT mainly adopted this type of integration; hence this chapter primarily looks at the challenges and opportunities encountered in this kind of collaboration.

In the other model of integration research is conducted within public health premises but participants are seen in separate research facilities. There is an overarching collaboration between researchers and government health officials. However they do not interact on a daily basis and the research participants are attended to separately from hospital patients. Research is removed from regular practice in this model, and whilst this can minimise some of the challenges it also reduces some of the benefits of the former model. Researchers may also have to work harder at disseminating and translating their findings into policy.

The integration of research in public health facilities is just one way of conducting biomedical trials. In other places of the world there has been a rapid growth of free-standing research facilities which support industry-sponsored commercial research. Petryna (2009) documents the ways that commercial medical science, with all its benefits and risks, is being conducted in such facilities and how it impacts on local health systems and emerging drug markets. Whilst we can draw some parallels from Petryna's analysis it is also important to recognise that her work describes and for-profit research conducted primarily by contract research organisations. The research conducted by public health collaborations like KEMRI/CDC has different goals and is accountable to global sponsors, some of whom are

philanthropic bodies. One core dilemma is however cross-cutting, namely questions of distributive justice which arise when research is conducted in places where the standard of routine healthcare is constrained by a lack of resources. In fact there are some who would argue that research should only be conducted in places where the health systems can provide the same level of care provided by within research trials (de Cenival, 2008). Whilst this extreme position appears morally defensible, it is also impracticable and may extend the 10/90 research gap - *where research and development expenditure is concentrated in the North with only 10% of health research money spent in the South although 90% of disease resides there* (Edejer, 1999) - and preclude developments which could strengthen health system capacity. In practice the question facing those seeking to redress the 10/90 health research gap is: *How can research protocols be applied equitably in resource-limited settings in view of inherent differences in access to human and material resources?*

This is a huge challenge and my aim in this chapter is to contribute to a clearer formulation of some of the constituent problems. I will draw on practical examples to elucidate these complexities and to demonstrate how the integration of research into public health facilities depends on close collaboration between researchers, health officials, health professionals and community representatives.

## **Collaborative Partnerships & the Conduct of Trials**

Partnership has become a dominant paradigm within the field of global health and has been defined by Buse & Walt (Buse and Walt, 2000) as '*a collaborative relationship which transcends national boundaries and brings together at least three parties, among them a corporation (and/or industry association) and an intergovernmental organization, so as to achieve a shared health-creating goal on the basis of a mutually agreed division of labour* (p. 550)'. This definition captures the relationships between sponsors, research organisations and governmental bodies in the conduct of medical trials but does not encompass the broader community who are included within the Emanuel et al (2004) framework. This framework describes six constituents of collaborative partnership: local representation; sharing responsibility in decision-making; mutual respect; minimization of disparities

between researchers and sponsors from developed countries and host communities; fair benefits for the local community; and fair distribution of the tangible and intangible rewards of research amongst partners (Emanuel et al., 2004). Partnership is understood in broad terms. However in practice the role and remit of community representatives in the conduct of trials can vary across research sites.

Collaborative partners must address key questions in the implementation of research: where will trials take place, how will competing interests and demands be managed, and how will ethical issues that arise in the conduct of studies will be resolved? Efficacy trials in particular need to take place where the target diseases are most prevalent and where general health and socio-economic indicators can be poor. These realities combined with limited social and health infrastructure mean that investigators must balance ideals and practicalities in decisions about where to situate trials. Many public health scientists prefer to integrate their work into public health facilities in order to promote capacity-building and better care for all children. Simultaneously in the evaluation of an experimental therapy they need to prioritise the safety of individual participants and maintain high scientific standards in order to comply with trial standards and regulations. This leads to the emplacement of 'global science' within local public health settings and the juxtaposition of two paradigms of care giving: 'research' and 'general'. In this situation, the way that researchers and collaborators manage competing demands and negotiate differences determines the level of blending that is feasible, from full integration, to partial integration or complete separation, where research takes place outside of public health facilities.

### **The 'Where' of Science**

Social studies of science have long drawn attention to the ambivalent relationship between scientific enquiry and location. The 'where of science' is however beginning to gain importance as a category of analysis in determining the legitimacy of knowledge. Thomas Gieryn (2002) describes the 'laboratory' with its intrinsic epistemic virtues of precision and control versus the 'field', where unadulterated reality lends credibility to scientific claims. The relationship between the two is subject to debate with some arguing that the field must in effect become a laboratory before it can serve as an authoritative space for knowledge making (Latour, 1999), whereas others make a case for preserving and drawing on both field



and laboratory simultaneously in a complementary way (Gieryn, 2006). In an ethnography of applied agricultural science, Henke (2000) refers to 'making a place for science' arguing that not only are the lines between laboratory and field blurred but that science must address the local context. For Henke (2000), the way that researchers interact with the 'lay public' dictates the practice of making a place for science and governs the extent to which science shapes these locations. This type of engagement can take on particular importance when research is conducted in African health systems, because the encounter between scientists and their (lay and professional) public is overlaid by differential access to resources, technologies and expertise. Space is here a matter of inside and outside, in terms of access to and exclusion from resources, healthcare expertise and care-giving which is not immediately available within the local system.

The geography of African economic engagement is discussed by Ferguson(2005) who argues that current political-economic conditions have resulted in resource-rich enclaves becoming a central element of social organization. In transnational medical research boundaries are not drawn so unambiguously, and the interests that sustain or transcend boundaries between research and general care are not as simple as in the economic practices explored by Ferguson. Importantly, the boundaries are often challenged by the fundamentally humanitarian and inclusive ethos of public health scientists. The conduct of world class research on the other hand requires researchers to work under scientific standards that differ from those of the field in order to comply with international standards and regulations, communicate with international partners and sponsors and complete administrative duties. To accommodate these requirements, distinct spaces generally need to be made either within or alongside field facilities, so that research duties can be accomplished and participants' safety ensured. These conflicting pressures require researchers to combine immersion in local realities with demands to maintain international standards. In many instances this results in differences between the care-giving provided to research participants and general patients. For example, even where researchers tend to sick participants within a general hospital ward alongside other patients, their higher patient-to-staff ratios means they can monitor research participants more closely.

As noted the juxtaposition of clinical research in regular health facilities can accentuate pre-existing differences in standards of care and access to resources. To negotiate these

differences, boundaries may be formed to demarcate spaces of science from those of everyday health-care. These physical and social boundaries are not necessarily visible and may be shaped by the participation of research and general health workers, patients and/or others who observe practices in the clinic. This boundary work raises ethical questions that need to be addressed throughout the conduct of trials.

Mindful of these differences, this chapter focuses on a hospital ward and clinics involved in the MVT. My aim is to explore the problem of difference at micro level in order to learn from the experiential experience of researchers and hospital staff and to throw analytical light on questions of trust, interpersonal relationships and distributive justice. Whilst these questions are not new to ethicists and social scientists little has been written about the way that differences in care-giving and assets are negotiated in collaborative transnational research, and how decisions are made about the use of space and resources. The contribution of this chapter is an analysis of these negotiations in a setting which is very distinct from the commercial research sites based in the United States, Brazil and Poland, which are the subject of other important ethnographic work (Petryna, 2009).

## **Documenting the Experiential Practice of CE in Public Health Facilities**

### **Framework of Collaboration**

Several formal processes are followed to establish and maintain collaborations between KEMRI/CDC and public health facilities. These include meetings between governmental health officials, the district health management team, health facility committee members and senior researchers. Written memoranda of understanding (MOU) are then formulated to *'...demarcate the points of agreement between "X" health facility and the KEMRI/CDC Research and Public Health Collaboration with regards to (reimbursement) /facilitation of patient care, (rent/space), electricity, provision of water and staff support, as applicable. It delineates general guidelines for both participating parties and outlines their roles in the various patient centred activities.'* In essence these written memorandums indicate that there is an awareness of the problems and challenges which can be encountered when research is integrated in public health facilities.

The terms of agreement cover issues relating to staff, medical care for trial participants, access to data, pharmacy arrangements, space arrangements, access for study monitors, equipment and electrical power, water supply, reimbursement to facilities where relevant, the relationship between parties, good faith and fairness, confidentiality, giving of notice and regular meetings of the parties. The MOU (Appendix II, Doc. 9) states clearly that KEMRI/CDC staff can only assist other health facility staff when they have completed their study duties. The section about the relationship between parties emphasizes the autonomy of each party, and stating that each is in complete control of their own operations and not subject to one another. The MOU documents that the study will maintain a separate formulary with some drugs that would not be routinely available at the hospital which can be used for non-study participants on a case-by-case basis at the discretion of the Principal Investigator of the study.

Whilst the MOU provided the framework for collaboration in the MVT many of the details were worked out in everyday encounters. According to my interviewees these encounters were not always easy; however a shared ethos to preserve and save life created the basis for collaboration.

*'Paperwork can wait, if you look at KEMRI/CDC and MOH (Ministry of Health) what is the bottom line, to save lives, and all of us who went through school, when you qualified that is what you swore, you know you go into this profession to save lives, so research or no research number one is safety.'*

*Male Research Nurse, RS 15*

### **Benefits of Collaboration**

Research was described as a *'window of opportunity'* by those working in health facilities which face significant constraints in the delivery of health services.

*"We are aware that the government of Kenya has brought us to the hospital here as staff, both technical and non-technical but with the present economy it is just not enough to, to have enough staff, to have enough materials, to have enough infrastructure [mmm]to be able to give that ideal quality care [right] to the patients [mmm]"*

*Male Medical Superintendent, CR 53*

The following benefits were attributed to the integration of research into public health facilities by researchers and hospital staff:

- Infrastructural renovations
- More qualified staff (including specialists) present within the health facility
- Researchers share resources and expertise when there is a shortfall
- Access to medical information via research internet connection
- Improvement in standards of care within the paediatric ward and reduced mortality (KEMRI/CDC, 2009)
- Researchers assist with difficult and emergency cases

Some questions were however raised about whether research benefits extend sufficiently to non participants and the wider community. Hospital staff would have liked research budgets to cover more supplies for general use in the wards. Similarly, health facility committee members thought that the free health-care provided to trials participants should also be made available to their families.

*Even if it is not the whole community, but it should be spread out just to a level of a family of or a homestead, but you know this one is restricted just to an individual not even the siblings*

*Male Health Facility Committee Member, CR 19*

Overall however, community representatives, health officials and hospital staff highly valued the benefits afforded by collaboration with KEMRI/CDC.

### **Integration of Research into Public Health Facilities**

KEMRI and international collaborators, including CDC, have been conducting malaria-related research at SDH since the 1980s. Most of this research took place within the paediatric and maternity wards and the outpatients clinics at SDH. Observational studies evaluated paediatric and maternal mortality related to malaria, anaemia and HIV, assessed blood transfusion practices and validated an algorithm for integrated management of childhood illnesses (Lackritz et al., 1997, Perkins et al., 1997, Zucker et al., 1994).



**Photo 24: SDH Paediatric Ward**

Preparations for the MVT commenced in August 2008 with a pilot study in the SDH paediatric ward to pre-test treatment algorithms, diagnostic procedures and trial equipment. KEMRI/CDC staff identified potential participants from the acute bay and attended to them in beds located across the ward. In this way, the pilot study was embedded in general ward activities and there was very little separation. The research staff attended to all sick children who were admitted to the ward and offered other support where required. There were separate research meetings and the research clinicians followed up research participants closely but there were also joint continuing medical training sessions for both researchers and general ward staff.

The implementation of the pilot study was not without challenges. Amongst the most pivotal was the transfer of hospital staff to other wards, resulting in an increased work load on MVT study staff such that they were unable to meet study trial protocol-specific requirements. From the hospital administration's viewpoint, the presence of research clinicians and nurses was seen as an opportunity to distribute the limited hospital work

force to other places that suffered from inadequate staffing. When the medical superintendent took action to reverse this trend complaints were voiced by parents about the differentials in care-giving and time allocated to patients as between research and hospital staff. These differences became increasingly apparent as the study progressed and the researchers had less time to assist with general patients. The following quotation from a mother illustrates some of parents' dissatisfaction about variable health-care standards.

*'I saw a difference. there were wards that were for KEMRI/CDC, there you see they attend to the kids after every short time they test the child and then the second person has reached, they look at the kid after every 30 minutes you see someone coming with the kids file asking questions. That is very different from where we were on the other side. If one person [health professional] goes round in the morning at 9 and the other one will come at noon and the other at 3 in the night only, but KEMRI/CDC they look at these people after every short time.'*

*Female CM 07*

The vaccine trial investigators' intention was to remain fully integrated within the general functioning of the paediatric ward when the MVT started in July 2009. They were committed to building capacity and had recruited a study paediatrician who would provide mentoring on general ward rounds when her other duties permitted. However in order to reduce the perception of parents of non-study participants that their children were receiving less attentive care, the medical superintendent advised the MVT team to use a separate 6-bed bay based at one end of the ward to admit and attend to research participants. An adjacent bay at the same end of the ward was already in use by another transnational research team (University of New Mexico/KEMRI); hence this space was referred to as the place where 'projects' operate, in other words where research is conducted. The bay allocated to the MVT team was visible to other general patients through windows in the wooden panels that separate individual bays in the ward. When admissions exceeded the capacity of this bay, research participants are also attended to in other bays alongside general patients. Research nurses and clinical officers offered assistance to hospital staff when called upon, particularly in emergency cases (e.g. seizures, respiratory and cardiac arrest). However there was less interaction during the MVT proper than there was during the pilot study. As a result, differences in care-giving, for example the patient-to-staff ratio, are more evident. The ratio was 2 nurses and 1 clinical officer for 6-10 research participants versus approximately 42 patients for the same number and calibre of

government staff. Like the rest of the ward, research patients sometimes had to share beds. But the research nurses took care to separate children with contagious diseases from those at risk, and the area was kept clean by local personnel employed by the researchers. These small things can make a big difference to patients and their families' experience of care-giving during a hospital admission.

### **Distinctions in Service Provision**

As indicated above there are core distinctions in the aims and practice of research and general health service provision. In economically-deprived settings, general health-care providers provide essential services to the majority of the population. The standard of care is often constrained by staffing levels, access to resources and specialists (English et al., 2004, Wamai, 2009).

Health research and particularly clinical trials of investigational products have a primary objective of answering a specific scientific question in a manner that ensures participant safety. Trials must adhere to strict regulations and provide acceptable levels of health-care, which is usually the best standard possible in the particular setting. Generally, the staff/patient ratio is high, resources are readily available and trial participants receive individual attention.

Physical and financial access to health-care also differs between the two paradigms of research and general care. In Kenya out-patients services for children <5 years are free at the point of care. However frequent unavailability of medicines results in out-of-pocket spending on drugs and is one of the main reasons why people avoid utilizing health-care facilities (Ministry of Health, 2003). In-patient services are chargeable and the following rates applied in 2009: on admission to the paediatric ward at SDH parents paid Ksh 100 (approximately US \$ 1.20) for a patient file and basic amenities. They also paid a basic bed rate of Ksh 50 (US \$ 0.60) per night for supplies such as bed linen, gloves, dressings, cannulas and intravenous sets. Certain medications were free, such as antipyretics and first line antibiotics; others need to be bought at the hospital pharmacy or in town. X-Ray and laboratory investigations apart from HIV tests were chargeable for in- and out-patients and

amount to approximately 300 Ksh and 150 Ksh (US \$ 4 or 2) respectively. These user fees placed a heavy burden on households in an area where 60-74% of people lived under the poverty level (Kenya Central Bureau of Statistics, 2005), and where, according to one my research assistants, it cost on average Ksh 150 to feed a family of four.

All services, medications and laboratory tests were free for research participants whose parents were also given travel reimbursement (150 Ksh) to reduce any financial burden when they are expected to present to the study site for scheduled visits and any sick visits. On a case-by-case basis, KEMRI/CDC could also provide transportation between peripheral sites to SDH or facilitate transfers to tertiary facilities.

This analysis suggests that the core distinctions between care-giving in the research and the general paradigm concern questions of cost, level of attention and whether services are individualised and specialised or more generic and essential.

### **Challenges in Practice**

In practice the integration of the MVT within SDH and the peripheral health centres resulted in key challenges in terms of physical constraints, sharing of working spaces and accessing resources. It was also evident that those in charge of these facilities considered themselves to be answerable to the government and the local community. They were careful to ensure that research was conducted in an ethical manner, did not interfere with routine services and did not increase waiting times or damage their reputation.

*'...and we are talking to them, first of all, we want to see whether this research they are bringing into the hospital has any ethical issues [mmm], that would eeh (yes), that would bring us into conflict with the law'*

*Male Medical Superintendent, CR 53*

### **Physical Constraints**



Space has to be found within facilities stretched beyond capacity, so researchers renovate areas and contribute to new structures. At SDH, research partners have also pooled resources to construct a separate building to absorb research activities, house HIV care and treatment services, and create a hospital conference room. This clinical research centre is being built to strengthen the research capacity at SDH but half of the space will also be used to extend hospital services.

*'...we are calling it the annex [the annex], so for CDC, they are seeing, the KEMRI/CDC are seeing it as a clinical research centre [ok], the hospital is seeing it, is seeing it as a patient support centre, a resource centre [mmm]. Maybe somebody else is seeing it differently; everybody is looking at the same thing differently...'*

*Male Medical Superintendent, CR 53*

There are concerns at SDH about establishing separate spaces for research within the grounds of a public hospital. Facility managers argue strongly that research patients should be cared for in the regular wards and that any improvements should benefit all patients. Researchers similarly express the desire to continue to strive for integration and do not want a new structure to result in segregation. At present there are no plans to move in-patient study participants off the hospital ward. Careful engagement will be required to negotiate differing expectations.

### **Social Experience of Space**

The integration of the MVT into the paediatric ward increased staffing levels and resulted in a reduction of paediatric mortality (KEMRI/CDC, 2009). Despite these evident advantages it was also apparent that communication between ward-based research clinicians and nurses and hospital staff was impeded by a 'superiority/inferiority complex'. Greater status was attributed to working with a research organisation than with the government. In interviews both research and general staff talked about perceived differences in employment benefits, professional advancement, medical management and the need to respect for peoples' experience regardless of their status. Government hospital employees are permanent and pensionable members of staff whereas research clinicians are usually employed on annually renewable contracts. Pay scales and employment allowances are marginally better for

researchers; however they do not enjoy the same level of job security. These differentials do not fully explain the enhanced status attributed to those working for KEMRI/CDC. What matters more is research nurses' and clinicians' association with a successful and powerful organisation, which enables them to provide high quality care and achieve their professional aspirations.

*'...that even when you are internally motivated external factors such as poor facilities, lack of resources, your salary can lead you to become demoralized because you cannot reach your potential and apply your learning whereas in research you are given the training and tools you need to do a good job'*

*Male Research Nurse, RS 12*

Time pressures are common across both the research and the general care-giving paradigms. A significant proportion of MVT researchers' time was taken up with paperwork which hospital staff find difficult to reconcile in view of the high turnover of general patients. Hospital staff also talked about there being a 'project' side and 'their' side and stated that project patients did not want to be attended to by them in case they do not provide the 'special stuff' (*Hospital Clinician, CR 40*). Such attitudes can be difficult for senior hospital staff to reconcile since they are responsible for the overall running of hospital wards.

### **Sharing Resources**

MOUs are not explicit when it comes to the sharing of equipment and pharmaceutical resources between research projects and regular health services. Maintaining oversight over resources is not always clear cut as arrangements for oxygen supplies suggests. During the MVT research and hospital teams agreed to take turns in filling the cylinders to ensure a ready supply. When this arrangement lapsed, research staff found themselves in a difficult position for '*...you know oxygen is life saving refusing somebody oxygen is refusing that person life, it is actually in the medical ethics it is actually a crime*' (*Female Research Nurse, RS 16*).

All may have concurred that '*the spirit of the MOU is to share resources when hospital has a shortfall*' (*Medical Superintendent, CR 53*), but the circumstances and the cost of the

shortfall also played a role in decisions about resource distribution. It is easier to distribute new IV cannulas at Ksh 50 (US \$ 0.60) a piece than oxygen cylinders which cost KES 6000 (US \$ 80) to refill. In this instance, the MVT researchers informed the trial sponsor that they had to incur this cost because it would be unethical to deny oxygen.

Decisions about resource distribution, including the provision of medications not available within the hospital formulary were the responsibility of the MVT Principal Investigator (PI). In practice PIs usually entrust these decisions to facility-based researchers who respond liberally and seek to help whenever possible. Where significant costs are involved they consult with their supervisors and triage on the basis of severity of condition and personal circumstances.

### **Perception of Difference: “You are now special, you are under research”**

One of the clinical researchers described how uncomfortable it can be working in an environment where differences are so evident. One operates within one facility but to all intent and purposes the paradigms of research and general care-giving can seem poles apart. A hospital clinician likened coming from the ‘other’ side to the ‘project’ side as moving from the developing to the developed world. Similarly, a research doctor compared participation in the MVT with a medical insurance system. Based on her experience she maintained that trial participants attend hospitals earlier than general patients since they are not constrained by financial obstacles, and are assured of specialist paediatric services and attentive nursing care. Parents of other sick children noticed these differences and asked the researchers:

*‘What is this all about? And we tell them this is research, these are participants in a clinical trial and we have to do these kinds of things. They will understand but then when you look at them you can feel like why wasn’t I taken for the study? We respond by saying; it is not all children that fit the criteria.’*

*Male Research Clinician, RS 15*

Community representatives and hospital staff suggested that researchers sometimes reinforce this sense of exception in how they treated research participants and in the logistics of accessing hospital care.

*"...in fact they (researchers) call them, they tell them on admission that they are now special [right], they use that word special [they use the word special?] yeah, you are now special, you are under research"*

*Hospital Nurse, CR 34*

*"But when it comes to a research client, it's just a, it's just a, I don't know, you don't buy anything, at the end of it you are given transport back home [right], and with the government client, you buy everything, ok the service you get, but at the end of it, you pay for everything..."*

*Hospital Nurse, CR 36*

The researchers' perspective was that they were fulfilling their professional responsibility in line with Kenyan MOH guidelines and research procedures. Here it is important to note that treatment algorithms do not differ between the paradigms since both researchers and government health employees follow MOH guidelines. At the same time it is evident that researchers take great pride in their work and may communicate this to their clients thereby inadvertently drawing attention to existing disparities in care-giving. The discomfort expressed in the quotations above may have been less apparent had general standards of care and staffing levels been better in government facilities.

## **Management of Difference**

Most interviewees were in support of the integration of research within public health facilities, although it was clear that the MOH hospital-based staff we talked to did not fully concur with the hospital manager's view that *'perceived differences in standards of care are just a hiccup in contrast to overall benefits'* (CR 53). They appreciated the infrastructural improvements, additional staff and training opportunities. But they raised concerns about differentials in care-giving between trial participants and general patients. Researchers also struggled to reconcile this and some stated it would be easier if there were a separate research ward. The discrepancies would have been less obvious and they would not always have wondered *'what are the other patients thinking?'* (Female Research Clinician, RS 17). The improvement of governmental health facilities was also suggested as a means to facilitate more equitable research.

The integration of research into public health facilities raises questions that do not only occupy staff at the KEMRI/CDC site. According to a senior KEMRI/CDC researcher, some African trial sites are also debating this issue and some are moving towards conducting research in separate spaces due to similar challenges.

## **Discussion of the Main Themes**

This description of the operation of two different paradigms of care-giving within one health facility raises questions about how to integrate research, manage difference and make ethical decisions of clinical import in this context. In the case of the MVT, researchers were fully committed to a model of integration which meant research was very visible and required close collaboration between research and hospital staff. However the logistical and scientific demands of the trial, and the challenges confronted in the clinical setting, required them to draw partial boundaries between research and general health-care practice. The formulation of an MOU provided a framework that sought to extend the benefits of research whilst underlining the autonomy of both agencies who were party to the agreement. However the spirit of the understanding with such agreements is more difficult to capture and can be interpreted differently depending on a given individual's judgement of merit. Researchers need to apply protocols that confer boundaries both in terms of the provision of care to participants during and after the trial and the limits of these benefits. For example, trial participants' siblings or the neighbours of research participants who are not taking part in the research are not eligible to receive the same care due to cost implications, although they do benefit from improvements to local health facilities. Whilst on paper these boundaries appear sensible and justifiable, in practice it can be difficult to reconcile differing standards of care-giving for hospitalised research patients and general patients suffering from the same conditions. Researchers do of course intervene in cases of life and death and in many other incidences; however there are limits to the extension of benefits that can seem to be contrary both to the ethical impulse of medical practitioners and broader communitarian values.

This underlines the difficulty of shifting moral responsibilities from the political/structural domain into that of personal relations or even professional ethics. Health practitioners make public oaths in which they swear to do their utmost to preserve life in all situations. This commitment should be met with a mutual pledge by governments to commit the resources necessary to provide essential and equitable health-care. Governments, research sponsors, pharmaceutical companies, researchers, health practitioners and local communities need to have an open dialogue about what is required to conduct ethical and equitable research. Whilst there may be no straightforward answer to the question of who is responsible for raising standards in public health facilities, it is clear that, within collaborative partnerships, government bodies need to be more engaged in capacity-building efforts.

In the MVT, research sponsors channelled capacity funds through clinical trial alliances or allocated specific research funds to renovate the premises where the trial took place, so that, whilst the paediatric ward at SDH was described as dilapidated at the start of the MVT, renovations and increased staffing levels resulted in reduced mortality rates (Alsop, 2009). On the other hand, general hospital workers at SDH still face shortages and are not always able to provide the same standard of care as researchers. Hence the situation of research within clinical settings simultaneously extends benefits and demarcates differences in terms of practice and economics.

In practice, research is demarcated through social and spatial boundaries. While the latter are more visual the former can be more significant in terms of fostering collaboration. These boundaries pertain to position, responsibilities, interpersonal relationships, the repute of science and access to health-care resources. Collaborative agreements are not always explicit about how resources can be shared between research and regular services. This can result in critical decisions being made by research clinicians on a case-by-case basis. In such instances researchers tend to form their own boundaries of ethical activity based on their clinical judgement, personal moral reasoning and understanding of contextual issues (Wainwright et al., 2007). Whilst commendable and unavoidable in emergency situations a more inclusive deliberation of such dilemmas before or after the event would serve to strengthen relationships between research and hospital staff.

Within the context of collaborative partnerships several questions need to be addressed. First, is an element of partial separation between research and general care inevitable? If, yes, how can we ensure that this does not lead to a decrease in improvements to clinical care and services for non-research patients? Clearly, the separation between research and regular health services does not square well with the communitarian values of reciprocity, equity, and justice. At the same time, how do researchers accommodate difference and formulate boundaries of ethical scientific activity, and how are these understood in the context of collaborative partnership? There is a need for more open discussion about these issues between researchers, hospital staff, sponsors, ethicists, patients and community members. Finally, and of vital importance, who is responsible for raising standards of care in public health facilities? Improvements in the capacity and quality of public health services would go a long way towards reducing the differences encountered between research and general care.

Ten years after Edejer's (1999) appeal to reverse the health research funding gap between neglected diseases and diseases more prevalent in industrialised countries, progress has been made to develop safe and effective interventions that can redress the burden of disease in developing countries. In turn this has focused attention on the regulation of clinical research and the protection of potentially vulnerable populations. Guidelines are useful in the formulation and review of research; but guidelines alone cannot capture all levels of ethical decision-making. Practitioners must develop their own personal or collective strategies to address recurring dilemmas that occur in this context. Such dilemmas merit urgent public articulation and negotiation at all levels - hospital, district, national, and international - to consider how differences in access to resources and care-giving can be addressed and minimised or ameliorated to create better solutions.

## **Chapter 12: Summary & Conclusion**

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### **Introduction**

In this thesis I have explored the practice of CE in health research taking place in a resource-limited setting from as many different angles as possible in order to understand the work that CE is meant to do according to different people and groups who have a stake in it, and the work that it actually does. I have critically interrogated the assumptions and meanings behind this mode of intervention and documented CE's power and social effects. The purpose of this chapter is to synthesise the main findings and formulate an overarching conclusion, with reference to relevant literature and due consideration of the implications for the practice of CE of my findings and conclusion.

### **Summary of the Main Findings**

To present this summary of the main findings I have organised the eight findings chapters into three parts: 1) 'The Historical Emergence & Framing of Community Engagement' (Ch. 4-5); 2) 'The Social Construction of Community Engagement' (Ch. 6-9); and 3) 'Responses and Negotiations in Community Engagement' (Ch. 10-11).

### **Historical Emergence & Framing of Community Engagement**

In chapter 4 I discussed how, within a time-span of 30 years, the KEMRI/CDC research programme evolved from a relatively small outfit undertaking small-scale studies primarily focussed on malaria prevalence and treatment, into a global project carrying out numerous clinical trials and observational studies at any given time. I argued that research which was initially hosted by and accountable to district or community-led health and development programmes became increasingly externally driven. This gradually altered the exercise of control and the direction of interactions between researchers and community members.



Community members became primarily the sample frame, or in some cases, the facilitators of research rather than instigators of and collaborators in public health programmes and related research. The fact that the community was no longer integral to the running of research programmes yet still essential as participants created a progressive distancing and disconnect which, by the early 21<sup>st</sup> Century, culminated in rumours as well as in public debate and negative media reports. From this train of events emerged the realisation that CE was not there by default, but had to be attended to in order to maintain support for their programmes and respond to increasing demands for accountability. Consequently researchers assumed responsibility for CE and appointed community liaison and communications officers.

The contemporary framing of CE at KEMRI/CDC, described in chapter 5, suggests that CE is primarily about researchers reaching out to the community in which trials take place - principally by conveying information and teaching laypeople about science - rather than pursuing a more balanced reciprocal partnership. The latter is an implicit assumption in the theoretical of conception of CE, and the foundation of its assumed social value as a tool of ethical research practice (see chapter 1). This type of reciprocity seemed to be more evident in the earlier stages of community relations described in chapter 4. In the contemporary framing of CE the local community is presented as separate from the KEMRI/CDC community. In this formulation 'community' comprises: those who need to know about the research programme; those who participate in or seek services from this programme; those who live where research is taking place; and community leaders and official collaborators who shape public opinion. Much emphasis was placed by KEMRI/CDC staff whom I interviewed on information exchange, transparency about the purpose of research and reaching out to as many people as possible. Other potentially important aspects of CE such as employment, health service provision and infrastructure building were less emphasised. KEMRI/CDC personnel are tasked with fostering good community relationships, and particular personnel are delegated direct responsibility for communication, collaborating with community leaders and forming representative bodies (such as CABs), which can help researchers apply protocols more effectively and with reference to community norms and values. CE is viewed as a learning process and something that has to be planned carefully in order to mitigate the influence of latent cultural idioms and related rumours. These rumours

clearly influence researchers' thinking about the local community and underscore boundaries and demarcations already drawn between KEMRI/CDC and the places where trials take place. The contemporary framing of CE at KEMRI/CDC thus presents CE as a way of facilitating the smooth operation of trials and countering negative rumours and opposition. The overall goal is to increase community members' knowledge of and familiarity with science, and the principal means employed is the delivery and exchange of information.

### **The Social Construction of Community Engagement**

The social construction of CE among different people working within KEMRI/CDC was elaborated on in chapter 6 by drawing on the experiences and thinking of different levels of personnel. As chapter 6 showed, the character of the KEMRI/CDC collaboration, and power dynamics both between representatives from the two organizations and within the two organizations influenced the public perceptions of the research programme and relationships with external partners. Promoting a positive image, giving careful attention to the content of information shared with the media and general public, and demonstrating 'attachment' to the local community were core features of the CE approach taken at KEMRI/CDC. FWs, whose job is to move between research structures and the target community, capitalised on their position as 'people of the community', and internally produced newsletters ('Voice of the Community') stressed the achievements of the KEMRI/CDC programme and the role played by local scientists. The use of colour photographs and expensive glossy paper communicated inadvertently, and somewhat countering the stated aims of creating proximity, something about the comparatively vastly superior wealth and status of the research enterprise in contrast to the community, and showed how the exercise of science can at once be demarcated from common experience and yet at the same time reach closely into people's lives. In a context characterised by poverty the notion of 'attachment' (demonstrating affinity in order to gain trust) can require researchers to demonstrate material solidarity with the local community in the practice of CE. This chapter reveals a tension between the emphasis on information exchange and the need to engage materially under conditions of poverty. The subsequent chapters also

document how the distribution of material benefits is central to the practice of social relations in this cultural context.

Chapter 7 conveyed how the role of VRs is shaped by ambiguities related to their employment status and their dual accountability to researchers and their villages. VRs are a 'hybrid' since they are not in the strictest sense volunteers but neither are they contracted KEMRI/CDC employees; they occupy the 'grey area that exists between voluntarism and paid labour' (Brown, 2011). As my main findings show VRs were careful to stress their commitment to self-less community service since it augments their respectability at community level and opens up opportunities for financial gain, exposure and self-development. VRs' position of being both with the community and with KEMRI/CDC emerged as advantageous for the conduct of research. However it was also clearly problematic in terms of exercising trust, balancing allegiances and adequately representing community views. VRs association with KEMRI/CDC and proximity to trial participants also required them to negotiate implicit and explicit expectations for material and medical assistance in a cultural setting in which much importance is placed on sharing and mutuality.

The concept of 'positioning' of people who travel across the imagined boundary between the community and KEMRI/CDC, which emerged in chapter 7, gained further prominence in chapter 8 on CABs. CABs are voluntary bodies whose mandate at KEMRI/CDC is to foster partnership between researchers and the local community. In practice CAB members highly valued their association with a modern and progressive project and assumed the role of KEMRI/CDC patron-clients rather than community advocates. Becoming a CAB member meant that they gained access into a circuit of knowledge about research activities, peripheral job opportunities and other developments. Hence, whilst CAB members help researchers to address local concerns and appreciate contextual issues, questions arise about their independence and ability or willingness to examine research projects critically.

In chapter 9 questions of context, power and unequal resources were driven home strongly by elected representatives and senior government administrators. They argued that one cannot apply a research agenda without accounting for inadequate health services and the

poverty of most trial participants. For them the material expression of solidarity was central to CE and provided the basis for ongoing collaboration. They also warned researchers against working in isolation, and stressed the importance of their own involvement as senior government representatives, and of improved communication and accountability. Chiefs, who represent the lowest tier of government administration, were more positive about their relationship with KEMRI/CDC. They felt that researchers understood the importance of their buy-in as leaders whose judgement carries significant weight at community level. Similarly to senior officials they also viewed research as a way of creating opportunities for development which could benefit their areas of jurisdiction.

### **Responses and Negotiations in Community Engagement**

Chapter 10 described the diverse spectrum of community responses and concerns which became evident during the course of the vaccine trials. My analysis showed that the passage of time was a crucial factor in CE, which is easily overlooked in the tight schedules of collaborative research programmes. My analysis revealed that as people started to interact more closely with KEMRI/CDC, they began to lay aside hesitations and inherent suspicions which were heavily influenced by latent cultural idioms, such as 'blood stealing' rumours. Their attention became increasingly drawn to the benefits of trial participation and questions of exclusion began to dominate public concerns. Mothers of trial participants highly valued the standard and nature of care given to their children and were keen to remain attached to KEMRI/CDC. Community members also observed the 'good' associated with the research programme and wanted benefits (e.g. free health-care) to extend beyond those directly participating. Despite a growing familiarisation with and acceptance of the research programme, misgivings however continued to surface. Partly arising from tensions within the local social fabric, notably gender relations, fathers in particular, demonstrated active and passive resistance to their children's enrolment or continued participation in the vaccine research. They perceived the balance of benefits as favouring researchers and associated participation with poverty which, in turn, reflected badly on their paternal responsibility to provide for their families. It was also evident that fathers had limited contact with the research programme and were rarely involved in consent processes.

While chapter 10 focused on engagements at community level chapter 11 shifted our attention to engagements within public health facilities. In particular it described how differences in health-care provision between research participants and routine patients were negotiated in the general SDH paediatric ward where sick MVT participants were cared for by researchers. Whilst researchers and their MOH counterparts were in principle committed to the integration of research in places where general routine care was being provided, boundaries between scientific practice and general care were drawn in order to facilitate practice. Two paradigms of care-giving - 1) 'research' and 2) 'general care' - were contrasted in chapter 11 in terms of therapeutic relationships, accountability structures, working cultures and access to resources. Collaborative agreements provided a formal framework but did not account for all challenges that arose within the spatial and social dynamic or in decision-making processes about sharing research resources. In chapter 11 I argued for a proper public articulation of these dilemmas so that problems of inequity are not transferred from the domain of collaborative operations to the domain of personal morality, but instead are continuously negotiated with all partners to achieve better solutions.

## **Overarching Conclusion**

Synthesised together these findings suggest that CE is socially constructed, context-specific and that it arises out of a particular history and framing of relationships between researchers and the broader community. It is also characterised by underlying ideas and assumptions about the nature of the 'community' and lay people, and distinct ideas about what 'engagement' with science and 'collaboration' in bio-medical research mean and involve. At KEMRI/CDC the 'local community' is viewed by staff as separate from the 'research community' and much emphasis is placed on information exchange in order to address differentials or deficiencies in experience and understanding on the community's part. My analysis suggests, however, that CE is more contradictory and complicated than a simple meeting or exchange between researchers and the community, or between scientists and lay people. Such meetings are characterized by evident power differentials, differential

access to resources, and related expectations of material assistance. Neglecting such tensions is not helpful since it tends to relegate community concerns to being seen as less important than the transfer of knowledge. This is counterproductive since as my findings have shown, material engagements, whether in the form of care-giving for trial participants, infrastructural developments at government health facilities, or support for community projects, result in increased acceptance of research and closer collaboration between researchers and community members.

This overarching conclusion underscores the fact that CE is enormously challenging in places where collaborative relationships are characterised by differential access to knowledge and resources. International health research is shaped by its access to substantial resources and the scale of this enterprise is particularly visible in resource-limited settings. Inequalities between collaborating research organisations and the community are highly conspicuous in such settings. To a certain extent these inequalities necessitate CE; however notions of 'partnership' can also deflect attention away from the hierarchy and dependency which inevitably underlies collaborative relationships in these settings. This means that inequalities and related questions of social justice are rarely voiced in CE activities. Consequently they remain unresolved. The awkwardness of this was very evident in the material which I have presented in this thesis. There is a pressing need to consider how these unresolved questions which arise during the conduct of international bio-medical research can be addressed from the ground-up.

Increasing emphasis is being paid by ethicists and health professionals to expanding the discourse on international health research ethics beyond interpersonal ethics to address more substantive questions about global health justice (Benatar and Singer, 2010, Macklin, 2008, Meslin, 2008, Farmer, 2005). My thesis adds weight to these calls for solidarity and closer consideration of the ways in which the benefits of medicine, science and technological innovation are distributed in the conduct of bio-medical research. The moral arguments for the interconnectedness of the research enterprise and global health justice have been convincingly presented by Macklin (2008) and Benatar and Singer (2010, 1998, 2000). Impatience is now being voiced about the pace with which the translation of good

arguments into action is occurring (Benatar and Singer, 2010, Meslin, 2008). Meslin (2008) suggests that global health justice will not be achieved in international health research without a bi-directional approach that involves capacity building both from the top-down and from the ground-up. Whilst he welcomes the top-down focus on the development of guidelines and policies which seek to harmonize global research ethics regulation, he also pinpoints their inadequacies in terms of local application. For Meslin (2008) research ethics capacity from the ground-up involves sitting down with research partners, administrators, ethics review committee members, research participants and the communities from which they come, to discuss and debate the terms, concepts and practice of research with due consideration of the local circumstances. He cites examples where ideas about fairness in research were explored with research participants and clinician-researchers and debated by international research collaborators working in Kenya. The latter informed the development of an institutional framework which sought to acknowledge openly inequities in the application of research within institutions and between collaborating institutions and to redress them proactively.

It is evident from this literature and from my thesis that questions of health and social justice need to be accounted for in the everyday practice of international research. The challenge that faces us now is how to expand the mandate of CE to debate such key underlying challenges of social justice and to identify practical solutions which can address these. Such extension could take on two directions, lateral and vertical. Laterally CE could include teaching community members not just about research but also about their human right to health-care, advocacy and political accountability. The vertical extension of CE recognises that researchers cannot address questions of social justice in isolation. Rather they need to involve funders, sponsors and national and international governmental bodies in order to achieve lasting change. CE in bio-medical research urgently needs to broach and debate interrelated questions about inequalities, health rights and accountability so that community members can participate in identifying solutions from the ground-up.

## **Closing Statement**

The central conclusion and argument of this thesis is that CE needs to be understood within the context of historical models for working with target communities, and the long-standing and developing relationships between researchers, their staff and assistants, and members of the wider community in which trials take place. Furthermore, far from being an unproblematic and unequivocal good in terms of ethical practice, CE offers a lens into new and pre-existing inequalities which have a detrimental effect on public health and the implementation of research in resource-limited settings. CE emerges from my data and my analysis as highly complex and immensely challenging work, which requires continuous efforts and cannot be limited simply to information exchange. In order to address the tensions and contradictions which arise in CE it is essential to discuss questions of inequalities and social justice openly and directly, and to engage materially, through a broader distribution of resources and by means of health advocacy, with the communities in which research takes place. There is a need to move way from 'engaging' the community on to an engagement with and behalf of the community. Only in these ways can CE achieve its fullest potential, and the course of research be steered along the correct path to the benefit of all.



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# Appendices

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**Appendix I:      Research Background & Methods**

**Appendix II:     Research Findings**

## **Appendix I: Research Background & Methods**

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### **List of Documents**

10. Centers for Disease Control: Principles of Community Engagement
11. Study Participant Details
12. Field Notes Excerpt, February 2007
13. AIDS vaccine conference in South Africa in October 2008, Poster
14. Chronology of Community Engagement in the Vaccine Trials
15. Comparative Observation Tools
16. RSTMH Biennial Meeting September 2012, Abstract of an Oral Presentation:  
*'We can't involve everyone': A Comparative Case study of Community Engagement Processes at two Malaria Vaccine Trial Sites in Kenya*

## **Appendix I, Document 1:**

# **PRINCIPLES OF COMMUNITY ENGAGEMENT**

**CDC/ATSDR Committee on Community Engagement  
Centers of Disease Control and Prevention  
Public Health Practice Program Office  
Atlanta, GA., 1997  
<http://www.cdc.gov/phppo/pce/part3.htm>**

### **Before Starting a Community Engagement Effort...**

1. Be clear about the purposes or goals of the engagement effort, and the populations and/or communities you want to engage.
2. Become knowledgeable about the community in terms of its economic conditions, political structures, norms and values, demographic trends, history, and experience with engagement efforts. Learn about the community's perceptions of those initiating the engagement activities.

### **For Engagement to Occur, It Is Necessary to . . .**

3. Go into the community, establish relationships, build trust, work with the formal and informal leadership, and seek commitment from community organizations and leaders to create processes for mobilizing the community.
4. Remember and accept that community self-determination is the responsibility and right of all people who comprise a community. No external entity should assume it can bestow to a community the power to act in its own self-interest.

### **For Engagement to Succeed . . .**

5. Partnering with the community is necessary to create change and improve health.
6. All aspects of community engagement must recognize and respect community diversity. Awareness of the various cultures of a community and other factors of diversity must be paramount in designing and implementing community engagement approaches.
7. Community engagement can only be sustained by identifying and mobilizing community assets, and by developing capacities and resources for community health decisions and action.
8. An engaging organization or individual change agent must be prepared to release control of actions or interventions to the community, and be flexible enough to meet the changing needs of the community.
9. Community collaboration requires long-term commitment by the engaging organization and its partners.

## Appendix I, Document 2: STUDY PARTICIPANT DETAILS

### I: KEMRI/CDC Staff Members (N=18, Series of two Semi Structure Interviews (SSI) =6, One SSI=12)

Table 3: KEMRI/CDC Staff Members (ID: RS=Research Staff)

ID	Gender	Age/Age Range*	Nationality	Position	Type of Interview	Date of 1st Interview	Date of 2nd Interview
RS 1	M	43	Kenyan	Community Liaison Officer	SSI	17-Feb-09	N/A
RS 2	M	30	Kenyan	Fieldworker	SSI	19-Feb-09	17-Sep-09
RS 3	M	57	American	Investigator	SSI	02-Mar-09	26-Sep-09
RS 4	M	29	Kenyan	Investigator	SSI	02-Mar-09	N/A
RS 5	M	45-54	American	Communications Officer	SSI	05-Mar-09	N/A
RS 6	F	25-34	Kenyan	Communications Officer	SSI	06-Mar-09	N/A
RS 7	M	25-34	Kenyan	Fieldworker	SSI	11-Mar-09	N/A
RS 8	M	25-34	Kenyan	Fieldworker	SSI	23-Apr-09	N/A
RS 9	M	27	Kenyan	Fieldworker	SSI	12-May-09	30-Nov-09
RS 10	M	32	Kenyan	Fieldworker	SSI	13-May-09	15-Jun-09
RS 11	F	31	Kenyan	Community Liaison for Vaccine Trials	SSI	19-May-09	30-Jun-10
RS 12	M	38	Kenyan	Technical Staff	SSI	19-May-09	N/A
RS 13	F	44	American	Investigator	SSI	17-Jun-09	02-Oct-09
RS 14	F	44	American	Senior Scientist	SSI	10-Aug-09	29-Jun-10
RS 15	M	35	Kenyan	Technical Staff	SSI	15-Sep-09	N/A
RS 16	F	16	Kenyan	Technical Staff	SSI	16-Sep-09	N/A
RS 17	F	54	International	Investigator	SSI	07-Oct-09	N/A
RS 18	F	25	Kenyan	Fieldworker	SSI	23-Nov-09	N/A

\*Age Range is given where the exact age at time of interview was not known

Summary Statistics: N=18, Female=7, Male=11, Kenyan=13, International=5

## II. Community Representatives (n=67, SSIs=28, FGDs=6)

Table 4: Community Advisory Board Members (ID: CR=Community Representative)

ID	Gender	Age / Age Range	Position in CAB	Who they represent	Type of Interview	Date of Interview
CR 2	F	35-44	CAB 1 Secretary	Women's Groups and CBOs	SSI	10-Feb-09
CR 3	F	55-64	CAB 2 Organising Secretary	Retired Teachers	SSI	11-Mar-09
CR 4	F	25-34	CAB 2 Secretary	Women's Groups	SSI	30-Mar-09
CR 5	M	45-54	CAB 1 Chairman	District Administration	SSI	31-Mar-09
CR 6	M	49	CAB Member	Disability Groups	FGD	11-May-09
CR 7	F	63	CAB Member	Women's Groups, CBOs	FGD	11-May-09
CR 8	F	33	CAB Member	Women's group (nominated councillor)	SSI	13-May-09
CR 9	F	39	CAB Member	Community Based Organisations (also VR)	FGD	15-May-09
CR 10	F	33	CAB Member	Traders	FGD	15-May-09
CR 11	F	42	CAB Member	Community Based Organisations	FGD	15-May-09
CR 12	F	60	CAB Member	Church Groups	FGD	15-May-09
CR 13	M	62	CAB Member	Retired Teachers	FGD	15-May-09
CR 14	M	64	CAB Member	Opinion Leaders	FGD	15-May-09
CR 15	F	34	CAB Member	Nurses (Health Workers)	FGD	15-May-09
CR 16	F	46	CAB Member	Church Leader	FGD	15-May-09
CR 25	M	43	CAB 2 Chairman	District Administration	SSI	15-May-09
CR 44	F	74	CAB Member	Church Groups	SSI	30-Jun-09

Summary Statistics: N=17 (Female=12, Male=5)

Focus Group Discussions= 2, Semi-Structured Interviews=7



**Table 5: Village Reporters (ID: CR=Community Representative)**

ID	Gender	Age Range	Type of Interview	Date of 1 <sup>st</sup> Interview	Date of 2 <sup>nd</sup> Interview
CR 26	F	43	SSI	25-May-09	12/10/09
CR 27	F	39	SSI	25-May-09	N/A
CR 28	M	61	SSI	26-May-09	27/10/09
CR 29	F	41	SSI	26-May-09	27/10/09
CR 30	F	25	SSI	27-May-09	5/10/09
CR 32	M	35-44	SSI	28-May-09	6/10/09
CR 37	F	61	SSI	02-Jun-09	N/A
CR 38	M	32	SSI	02-Jun-09	23/10/09
CR 39	F	27	SSI	10-Jun-09	28/10/09

**Summary Statistics:** N=9 (Female=6, Male=3)  
 Series of 2 Semi-Structured Interviews=7, Single Semi-Structured Interview=2

**Table 6: Gatekeepers: Government Administrators and Elected Representatives (ID: CR=Community Representative)**

ID	Gender	Age / Age Range	Position	Type of Interview	Date of Interview
CR 5 <sup>1</sup>	M	45-54	Chief, Area 2	SSI	31-Mar-09
CR 17	M	50	Chief, Area 3	SSI	19-May-09
CR 25 <sup>1</sup>	M	46	Chief, Area 4	SSI	21-May-09
CR 31	M	45-54	District Commissioner	SSI	27-May-09
CR 42	M	54	Chief, Area 1	SSI	29-Jun-09
CR 56	M	38	Assistant Chief	SSI	28-Jul-09
CR 57	M	53	Chairman of Council	SSI	03-Dec-09

**Summary Statistics:** N=7, all male, all Semi-Structured Interviews

1. ID CR 5 and ID CR 25 also listed in Table XX (see Footnote<sup>9</sup>)

<sup>9</sup> Participants ID CR 5 & ID CR 25 are listed in Table 4 and Table 6. They were each interviewed on one occasion but the material collected is relevant to both groups. Out of the 67 CRS listed, 3 were interviewed twice under different IDs: ID CR 12/CR 51-FGD as CAB member and FGD as Health Facility Committee member (see Table 4 & Table 7), ID CR 17/CR 52-SSI as Chief and FGD as Health Facility Committee member (see Table 6 & Table 7), ID CR 55/CR 70-SSI as Health Official and FGD as DHMT member (see Table 7).

**Table 7: Health Facility Partners (ID: CR=Community Representative)**

ID	Gender	Age Range	Position	Type of Interview	Date of Interview
CR 1	M	45-54	Hospital Matron	SSI	10-Feb-09
CR 18	M	64	Health Facility Committee Member, Area 2	FGD	20-May-09
CR 19	M	56	Health Facility Committee Member, Area 2	FGD	20-May-09
CR 20	F	46	Health Facility Committee Member, Area 2	FGD	20-May-09
CR 21	M	64	Health Facility Committee Member, Area 2	FGD	20-May-09
CR 22	F	48	Health Facility Committee Member, Area 2	FGD	20-May-09
CR 23	M	28	Health Facility Committee Member, Area 2	FGD	20-May-09
CR 24	M	35-44	Health Facility Committee Member, Area 2	FGD	20-May-09
CR 33	F	53	Nursing Officer- Maternity	FGD	28-May-09
CR 34	M	44	Nursing Officer-Paediatrics	FGD	28-May-09
CR 35	F	42	Nursing Officer- HIV Patient Support Services	FGD	28-May-09
CR 36	F	38	Nursing Officer- Maternity	FGD	28-May-09
CR 40	M	36	Medical Officer	SSI	23-Jun-09
CR 41	F	44	Community Health Worker/Cleaner, Area 3	SSI	25-Jun-09
CR 43	F	58	Health Centre Administrator, Area 3	SSI	30-Jun-09
CR 45	M	65	Health Facility Committee Member, Area 3	FGD	07-Jul-09
CR 46	M	63	Health Facility Committee Member, Area 3	FGD	07-Jul-09
CR 47	M	60	Health Facility Committee Member, Area 3	FGD	07-Jul-09
CR 48	F	26	Health Facility Committee Member Area 3	FGD	07-Jul-09
CR 49	M	34	Health Facility Committee Member, Area 3	FGD	07-Jul-09
CR 50	M	37	Health Facility Committee Member, Area 1-4	FGD	07-Jul-09
CR 51	F	63	Health Facility Committee Member, Area 3	FGD	07-Jul-09
CR 52	M	50	Health Facility Committee Member, Area 3	FGD	07-Jul-09
CR 53	M	43	Medical Superintendent	SSI	16-Sep-09
CR 54	F	53	Nursing Officer-Maternal Child Health	SSI	22-Jul-09
CR 55	F	57	Member of District Health Management Team	SSI	23-Jul-09
CR 58	M	36	Member of District Health Management Team	FGD	18-Nov-09
CR 59	M	37	Member of District Health Management Team	FGD	18-Nov-09
CR 60	M	41	Member of District Health Management Team	FGD	18-Nov-09
CR 61	M	35-44	Member of District Health Management Team	FGD	18-Nov-09

ID	Gender	Age	Position	Type of Interview	Date of Interview
CR 62	F	30	Member of District Health Management Team	FGD	18-Nov-09
CR 63	F	39	Member of District Health Management Team	FGD	18-Nov-09
CR 64	M	37	Member of District Health Management Team	FGD	18-Nov-09
CR 65	M	36	Member of District Health Management Team	FGD	18-Nov-09
CR 66	M	39	Member of District Health Management Team	FGD	18-Nov-09
CR 67	M	49	Member of District Health Management Team	FGD	18-Nov-09
CR 68	F	37	Member of District Health Management Team	FGD	18-Nov-09
CR 69	M	47	Member of District Health Management Team	FGD	18-Nov-09
CR 70	F	46	Member of District Health Management Team	FGD	18-Nov-09

**Summary Statistics:** N=38 (due ID 55=ID 70 see Footnote<sup>1</sup>) (Female=14, Male =24)  
Focus Group Discussion=4, Semi-Structured Interviews=7

### III. Parents/Guardians of Vaccine Trial Participants

(n=18, Individual SSIs=9, Couple SSIs=2, Family Interview=1)

**Table 8: Parents/Guardians of Rotavirus Vaccine Trial Participants (ID: RP=Rotavirus Vaccine Trial Participant)**

ID	Gender	Age/Age Range	Type of Interview	Date of Interview
RP 1	F (Mother of twins)	39	SSI	13-Mar-09
RP 2	F	24	SSI	16-Mar-09
RP 3	F	21	SSI	17-Mar-09
RP 4	F	40	SSI	17-Mar-09
RP 5	F	31	SSI	18-Mar-09
RP 6	M/F	25, 22	SSI (Parents interviewed together)	18-Mar-09
RP 7	F	30	SSI	18-Mar-09
RP 8	F	25	SSI	19-Mar-09
RP 9	F (Grandmother of participant)	56	SSI	19-Mar-09
RP 10	M/F	27, 20	SSI (Parents interviewed together)	23-Mar-09
RP 11	F	31	SSI	23-Mar-09
RP 12	M/M/F/F/F/F/F	20-60	FGD (Mother and 6 other family members)	15-June-09

**Summary Statistics:** N=20, Female=16, Male=4

**Table 9: Parents/Guardians of Malaria Vaccine Trial Participants (Malaria Trial Participant=MP)**

ID	Gender	Age	Type of interview	Date of Interview
MP 1	F	18	SSI	02-Jul-09
MP 2	F	23	SSI	11-Aug-09
MP 3	F	27	SSI	13-Oct-09
MP 4	F	27	SSI	24-Nov-09
MP 5	M, F	48, 27	SSI (Parents interviewed together)	26-Nov-09

**Summary Statistics:** N=6, Female=5, Male=1

#### IV. Community Members

Table 10: Community Members

ID	Gender	Age Range	Position	Type of Interview	Date of Interview
CM 1	F	44	Teacher in Roho Church	SSI	16-Jun-09
CM 2	M	28	Ajouga (Herbalist, and Traditional Healer)	SSI	01-Jul-09
CM 3	M	29	Project Coordinator of a CBO	SSI	03-Aug-09
CM 4	M	51	Vicar of an Anglican Church	SSI	15-Sep-09
CM 5	F	21	Mother of child admitted to SDH paediatric ward	SSI in a pair	07-Oct-09
CM 6	F	45-54	Mother in law of CM 5 (CM 5 & 6 were interviewed together)	SSI in a pair	07-Oct-09
CM 7	F	42	Mother of a child admitted to SDH paediatric ward	SSI	22-Apr-11

Summary Statistics: N=7, Female=4, Male=3

## **Appendix I, Document 3:**

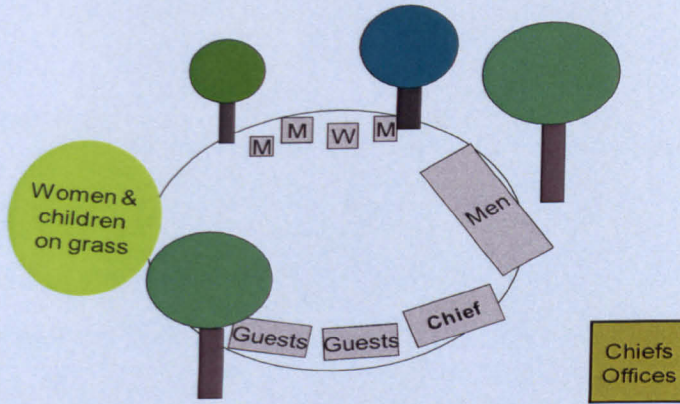
### **Field Notes Excerpt**

#### **Reflections on a Community Engagement Event which took place during my scoping visit to KEMRI/CDC in February 2007**

*During my scoping visit to KEMRI/CDC I was invited to attend a community meeting during which community members would be nominated to become CAB members for an infant Rotavirus vaccine trial (RVT) within a couple of months. The rural area where the RVT was going to take place question had not previously hosted KEMRI/CDC projects although the research institution is well known throughout the wider district. Prior to this meeting project leaders including the American trial manager, who will be referred to as John, the American field coordinator, Emma, and the Kenyan Community liaison officer, Sam, had met with the chief and sub chiefs of the locality to outline the purpose of the trial and the reasons for setting up a CAB. Accordingly the chief had mobilised community members to congregate in the place where he usually holds weekly 'barazzas'. A 'barazza' is the vehicle for discussion of community concerns, solving disputes between neighbours and communicating administrative and political measures and regulations. John, Emma and Sam had planned how the process of nomination would be organised and had scripted the message that they would communicate in advance. Emma would lead and Sam would translate each section of the message in turn.*

*When we arrived at the chief's baraza in the CDC vehicle a large group of people had already congregated and were sitting in a circle around the tree listening to other community notices. We were welcomed by the chief, who was dressed in his full uniform which resembles a soldier's outfit. We exchanged introductions in his office before we were led to the 'barazza' and seated in prime positions.*

## Community Meeting Setting



The meeting was in full swing on our arrival but some people were still gathering. The above diagram provides some insights into gender dynamics and social order. Women especially those with children sat on their lessos or kangas on the grass, some older women sat amongst the older men on chairs and benches. Not many younger men were present at this meeting, and those who came tended to stand in the background where their bicycles were parked. On our arrival a lady representing a non-governmental organisation was telling the gathering about a project to support families of children with learning disabilities who were looking for community mentors for affected families. Emma looked at her watch as she waited for their turn to speak. We sat behind tables with a sound system at one end. Before the meeting was handed over to Emma and Sam the young people presented a sketch about HIV/AIDS. The story line was familiar and the most striking aspect was the crowd's enjoyment of the male lead performer's enactment of a young girl.

Then attention turned to Emma, Sam, John and I who were introduced by the Chief as representatives of CDC. Emma, who is an outgoing, highly intelligent young woman in her mid twenties, greeted the gathering in Dholuo which was highly appreciated by the crowd (Emma previously worked as a Peace Corps Volunteer in nearby community for 2 years). This broke the ice and the ambience was positive even when Emma reverted to English to



communicate the scripted information. Amongst the crowd the prominent mother tongue would have been Dholuo with mixed levels of ability in spoken, oral, and aural English. Emma read separate portions of the text which Sam, a middle aged Kenyan of Luo origin, translated in to Dholuo in turn. In the middle of the message it became apparent to Emma that Sam had gone ahead of her and started to relate part of the next section before she had said it in English. This resulting tension would not have been visible to those listening in the crowd. Emma picked up and continued in the agreed sequence of the message, so one aspect would have been repeated, but this probably will have gone unnoticed by most. At the end of the message the chief helped Emma and Sam to explain the process of nomination for the CAB. People were separated into various groupings i.e. women's groups or churches and to decide on who to nominate from amongst these groups. This deliberation lasted about 20 minutes. Nominees names were then read out to the larger gathering who applauded them, and then the nominees gave their details to Emma and Sam. Overall the process appeared to go smoothly however I was left wondering whether the nominees were aware that they still had to go through a separate selection, interview process.

After this the meeting continues with other information being related by other guests or community members. We were led back to the Chief's hut where we were offered cold soft drinks and a meal of rice, ugali, chicken and beef stew. The Chief joined us and we conversed politely both about the event, future activities, the vaccine trial and community benefits i.e. the refurbishment and extension of the local clinic. I asked the Chief about the concept of harambee (community fundraising) and was told that both the chief's offices and the local clinic had been funded by means of harambee. After lunch we left. On the way back to Kisian, where all 3 have desks, then we visited other chiefs to make arrangements for other similar meetings. Leadership in these contacts was shared mainly between Sam and John and it was evident at times that Sam had had previous contact.

Back at Kisian, I unwittingly entered into a conversation between John and Emma about the fact that they, particularly Emma, were upset about Sam's translation. When I sought more understanding I was told it was not just about usurping the pre-defined format but it was also a gender issue. The Rotavirus study needed mothers collaboration so the lead should be taken by a woman and not a man.

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**Appendix I, Document 4:**

**Poster Presented at the AIDS Vaccine Conference in South Africa in  
October 2008**



# What Is Needed To Support Community Engagement?

Authors: T. Chantler<sup>1,2</sup>, J. Thomas<sup>1</sup>, W. Dwyer<sup>1</sup>, R. Squires<sup>1</sup>, K. Lammiman<sup>1</sup>, R. Dwyer<sup>1</sup>, R. Kumbhakar<sup>1</sup>, B. Storr<sup>1</sup>, W. Fawcett<sup>1</sup>  
 Institutions: 1. Meritrip Medical Research Institute; 2. London School of Hygiene and Tropical Medicine; 3. US Centers for Disease Control

## Background

- Administration of the Malaria investigational vaccine (MV201) was stopped in the Malawi/CTD/ROTCN 012 (STEP) trial in September 2007
- Data suggested V220 did not prevent HIV and may be associated with increased risk of HIV acquisition in men with pre-existing antibodies 1 immaturity and in unimmunized men

From *Lancet Infectious Diseases* 2009; 9(10): 620-621

## STEP 012/013

**Aids vaccine trials put on hold**  
 Local AIDS researchers, like others in the world, are stunned by the failure of what has been a major programme to find and test new interventions for their work on HIV. (APRIL 13, 2009) BY ANITA

## Critical Junctions in Progression for STEP 012 vaccine trial

- PIVSE 100 vaccine construction differed from V220 but also included a noninfectious adjuvanted 5 vector
- PIVSE 100 and adjuvant chosen how to proceed at 13 proposed sites in sub-Saharan Africa & the Americas
- Good participatory practice (GPP) guidelines state lay persons should be involved in decision-making at all stages of the research cycle

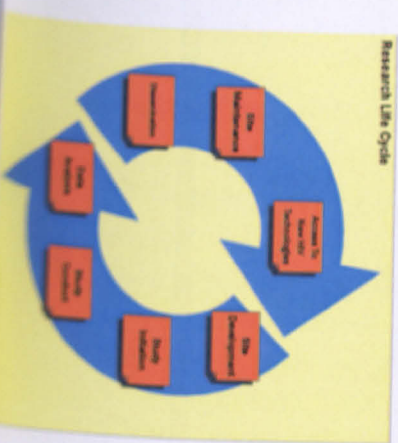
## GPP Guidelines & the Research Life Cycle

- A reference for those who conduct, fund, participate in and support such
- Contain 10 core principles

1. Scientific & ethical integrity
2. Respect
3. Clarity in roles and responsibilities
4. Towards shared responsibility
5. Participatory Management
6. Autonomy
7. More Transparency
8. Standard of Precedence
9. Access to care
10. Building research literacy

- Aim to promote effective community involvement throughout life cycle of a research study

## Research Life Cycle



## Methods, Process and Findings

Critical Incident Analysis is an educational research method that is used to reflect on professional practice. It was applied to consider a critical episode that took place at the KEMRI/CDC 2008 IIRI trial site.

The KEMRI / CDC Clinical Research Centre is based in the city of Kisumu in western Kenya



## Main Steps in Critical Incident Analysis<sup>1</sup>

1. Describe a Critical Episode
2. Interpretation of the Description
3. Discussion with Colleagues
4. Report Findings

## 1. Description of Critical Episode

- The episode occurred at the site development and study initiation stages of research life cycle
- Failure of the STEP trial required KEMRI/CDC staff to consider their ongoing participation in PIVSE 100

The description was based on data from and participation in conference calls and meetings focused on:

- Scientific & ethical just and costs of proceeding with PIVSE 100 based on available data
- Facilitating mechanisms of lay progression in decision-making process
- Taking note of the challenges faced by staff when they attended Community Advisory Board (CAB) meetings of STEP findings and their implications on PIVSE 100
- Ability of a questionnaire to assess community members willingness to participate in PIVSE 100 year 2 STEP
- How did this method result in data that could inform the institutional decision-making process?

## 2. Interpretation of the Description

- Reviewed as barriers to practicing GPP during this episode
- Interpretation undertaken by local staff

## 2. Discussion with Colleagues

- Discussion with co-workers during the development of the document

## 3. Findings

- Staff continued to believe the CAB about international decision-making concerning the status of PIVSE 100. The generalization arose at the wider public was not however substantiated due to concrete data:
- KEMRI/CDC staff members' ability to explain STEP results and their implications for PIVSE 100 to people unfamiliar with vaccine research
- This case shows an independent' ability to provide valid answers
- Timing of the message
- What was the value of the questionnaire when a conclusion on the scientific validity of PIVSE 100 had not been reached?

## What Were We Learning?

According to GPP guidelines community engagement at this critical junction is variable. While progress was necessary, however:

- The engagement of events and release of further 'STEP' data left field staff uncertain about the scientific validity of PIVSE 100
- Dialogue with the CAB was limited to communicating decisions made by the protocol team, trial sponsor and related scientific committees
- This left short of the shared responsibility' and participatory management' GPP principles
- Researchers lacked expertise skills and tools to explain the scientific issues at an appropriate level of understanding for lay persons
- The CAB was familiar with some research terms but was not able to follow advanced technological explanations

## What is needed to support community engagement?

- Communication tools that will facilitate public dialogue on scientific questions and build communication capacity to understand and inform research processes
- A debate on how lay perspectives can contribute to scientific decision-making
- Science in the era of DNA is advancing rapidly with promising prospects for improvements to public health
- Concurrently this progress makes meaningful engagement with lay persons more challenging
- Addressing shared responsibility amongst stakeholders in the context of such also becomes more difficult and raises the following questions
- Is 'shared responsibility' or complex scientific decision-making realistic?
- Researchers need support and training to be able to engage with community members from the earliest stages of trial and protocol development

## References

1. LINDAARD & ROUC (2007) Good participatory practice guidelines for household HIV prevention trials. UNAIDS. Stockholm

2. Steps adapted from an overview of Critical Incident Analysis: <http://www.cdc.gov/od/oc/media/press/2009/s090923.htm> (accessed 16p 2010)

## Acknowledgements

The staff and the community advisors based at the KEMRI/CDC HIV Research Branch in Kisumu, Kenya

KEMRI / CDC Clinical Research Centre in Kisumu, Kenya

The Community Advisory Board



## Appendix I, Document 5:

### Chronology of Community Engagement in the Vaccine Trials

This table shows all the CE events associated with the RVT and the MVT. Please note that my ethnographic fieldwork on these trials was conducted in stages (as outlined in chapter 1) with the most intensive part starting in October 2008 (when I received Ethics approval from the KEMRI Ethics Review Committee) and ending in December 2009. The events I observed and experienced in person before that date I have shaded in blue. Please note I was living and involved in projects at the KEMRI/CDC research collaboration from June 2007.

Rotavirus Vaccine Trial	Time	Malaria Vaccine Trial
<p><b>Community Preparations:</b></p> <ul style="list-style-type: none"> <li>• Project Manager and Field Coordinator (FC) consult gatekeepers</li> <li>• Educational seminar for chiefs</li> <li>• Team member delegated responsibility for community liaison for vaccine trials (CLVT)</li> <li>• Local field workers (FWs) appointed</li> <li>• Public informed about RVT at chief's barazas</li> <li>• Nomination of CAB members at barazas</li> <li>• Selection of CAB members by trial team</li> <li>• Training for CAB members</li> <li>• Meetings with village reporters (VRs)</li> <li>• VRs &amp; FWs inform households with pregnant mothers/newborns about the RVT</li> </ul>	<b>Jan-June 2007</b>	<b>Initial planning &amp; discussions with sponsors</b>
<p><b>July 6<sup>th</sup>: First Participants enrolled</b></p> <ul style="list-style-type: none"> <li>• Recruitment efforts increased; household visits, talks at barazas, clinics, churches</li> <li>• This time period was described by staff as one of '<i>intense rumour and misunderstanding</i>' <ul style="list-style-type: none"> <li>- Main foci of concerns; blood, potential harms and hidden agendas</li> </ul> </li> <li>• CAB meets and advises staff on how to address community concerns</li> <li>• Follow up of specific concerns at household level by FWs, CLVT &amp; FC</li> <li>• Specific interventions: <ul style="list-style-type: none"> <li><i>Blood Demonstrations and talks by participants from other trials at barazas</i></li> </ul> </li> </ul>	<b>July-Dec 2007</b>	<b>Protocol &amp; site development starts</b>

<p><b>January-April: Post-election Violence</b></p> <ul style="list-style-type: none"> <li>Local unrest &amp; population movements</li> <li>Non-Luo trial staff experience some problems accessing the local community</li> <li>KEMRI/CDC organises emergency medical camps in all areas where they work</li> </ul> <p><b>February: Recruitment Completed</b></p> <ul style="list-style-type: none"> <li>A total of 1008 participants enrolled=1<sup>st</sup> group of participants</li> <li>Community members informed by VRs, FWs, CAB Members and at barazas</li> <li>Frequency of CAB meetings reduced to quarterly (global budgetary decision at KEMRI/CDC)</li> </ul> <p><b>August: Second round of recruitment</b></p> <ul style="list-style-type: none"> <li>Trial asked to recruit 300 more participants=2<sup>nd</sup> group of participants</li> <li>Additional recruitment activities organised; barazas, household visits by VRs and FWs</li> </ul>	<p><b>Jan-Sept 2008</b></p>	<p><b>Protocol &amp; Site development</b></p> <p>Specific focus on preparations for the hospital based Pre-Mal study which will test clinical procedures, diagnostics, and equipment to be used in the MVT</p> <ul style="list-style-type: none"> <li>Meetings with hospital staff</li> </ul> <p><b>September: Pre-MVT Study starts</b></p> <ul style="list-style-type: none"> <li>Recruitment and CE activities mainly limited to hospital environment; specifically the paediatric ward</li> </ul>
<p><b>October: Recruitment completed</b></p> <ul style="list-style-type: none"> <li>1308 participants now enrolled in RVT</li> </ul> <p><b>19<sup>th</sup> November: 1<sup>st</sup> Annual KEMRI/CDC Results Dissemination Meeting</b></p> <ul style="list-style-type: none"> <li>To present and discuss findings with community, civic and medical partners</li> </ul>	<p><b>Intense Ethnography Starts</b></p> <p><b>Oct-Dec 2008</b></p>	<p><b>Nov: Study Coordinator visits the CAB</b></p> <ul style="list-style-type: none"> <li>To talk about Pre-Mal &amp; plans for MVT</li> </ul>

**Feb/March:**

**Feedback meetings-1<sup>st</sup> group of participants**

- To thank participants & provide information about the end of the RVT
- To inform them about upcoming trials
- Participants expressed concerns about continuity of care and receiving results:  
*'Can we get free gate pass into next trial?'*

**12<sup>th</sup> Feb: Community Stakeholder Meeting with Sponsors & Principal Investigators**  
*(referred to as Placebo Meeting)*

- Aim: Provide updates on the RVT, share experience from other African trial sites; explain technical terms; and create a platform for questions and related discussion.

**January**

- CLVT visits chiefs & schedules dates to speak about MVT at barazas
- Study Coordinator gives overview of MVT at District Health Stakeholders Meeting

**January- June**

- Regular barazas at chiefs' camps  
*-Questions focus on practical concerns & why trials can't benefit more people*
- Talks at churches, clinics, other groups
- VRs given info at their weekly meets
- Presentation at Head Teachers forum

**February:**

**1. CAB Hospital & Field Trial Sites Visit**  
Focus on MVT preparations & TB field work

**2. Special CAB training Meeting**  
Research ethics training & updates on trials

**May:**

**Training for MVT trial staff**

- PI states consent form developed with consideration of local context  
*(personal note: CAB was not involved)*

**Groundbreaking at District Hospital**

- Formal event involving hospital, KEMRI/CDC and district leaders. Celebrating the start of building work to create a new centre. This centre will provide more space for research facilities, improved space for HIV Patient support services and seminar facilities for hospital and research staff

**June:**

**Trial Information Leaflets piloted by FWs & VRs**

- Concerns raised about wording used to describe side effects and blood tests

<p><b>September:</b>  <b>Feedback meetings-2<sup>nd</sup> group of participants</b></p> <ul style="list-style-type: none"> <li>• To thank participants &amp; provide information about the end of the RVT</li> <li>• To inform participants about the MVT</li> </ul> <p><b>October-December: Future Plans</b></p> <ul style="list-style-type: none"> <li>• Results Dissemination Exercise planned and scheduled for January-February 2010</li> </ul>	<p><b>July-Dec 2009</b></p>	<p><b>9<sup>th</sup> July: MVT starts</b></p> <ul style="list-style-type: none"> <li>• Participants in older age group enrolled</li> </ul> <p><b>End of July/August</b></p> <ul style="list-style-type: none"> <li>• Five early withdrawals linked to concerns about venepuncture; <i>individual follow up</i></li> <li>• VRs feel disengaged; <i>has this led to a misrepresentation of MVT in community?</i></li> <li>• Strategic discussions between researchers and community liaison staff meet with VRs</li> </ul> <p><b>Recruitment progresses smoothly</b>  Rates higher in rural than urban areas</p> <p><b>November/December: Future Plans</b></p> <ul style="list-style-type: none"> <li>• Recruitment of infant age group scheduled for beginning of 2010</li> </ul>
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**APPENDIX I, Document 6**

**Observation Tools**

**a) Participant Observation Tool: Community Engagement Activities**

**Version 6<sup>th</sup> May 2009**

**b) Observation Tool: Malaria Vaccine Trial Consent Processes**

**Version 6<sup>th</sup> May 2009**

# Participant Observation Tool: Community Engagement Activities

## A. General information

Type of Meeting/Activity: \_\_\_\_\_

Date: \_\_\_\_\_ Time scheduled to start: \_\_\_\_\_ Time started: \_\_\_\_\_ Time ended: \_\_\_\_\_

Comments re start/end times: \_\_\_\_\_

Any additional activities, i.e. traditional dancers: \_\_\_\_\_

Place: \_\_\_\_\_ Observers: \_\_\_\_\_

Who called the meeting and why? \_\_\_\_\_

### Community leaders/officials in attendance:

Type of leader	No	Specify, details where applicable
a) Chief		
b) Sub chief		
c) Other District Admin Rep		
d) Village elder		
e) Ministry (Health, Agriculture etc)		
f) Health Facility Committee		
g) KEMRI or KEMRI/CDC staff		
h) CAB members		
i) Village reporters		
j) Other participants, NGO's, CBO's		

### Approximate attendance:

At start: Men \_\_\_\_\_ Women \_\_\_\_\_

At end: Men \_\_\_\_\_ Women \_\_\_\_\_

School aged Children \_\_\_\_\_

School aged Children \_\_\_\_\_

### Description of group composition; gender, age

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

### Sketch of seating arrangements

**B. Information given during the meeting**

Information givers, name, position in KEMRI or KEMRI/CDC projects:

KEMRI and other collaborators: \_\_\_\_\_

KEMRI/CDC: \_\_\_\_\_

Others: \_\_\_\_\_

Information	What & how was info shared i.e. flip chart, read, summarized, were brochures distributed, how interactive?	Language	Time taken
<b>KEMRI/CDC Projects</b>			
Mal 55; RTS,S Phase 3			
Rotavirus			
Other, Specify			
<b>KEMRI &amp; other collaborators Projects</b>			
<b>NGO/CBO Projects</b>			
<b>MoH or Gov Administration</b>			

### **C. Community Reactions**

1. What was the mood of the group (any indication why)?
  - a. At the beginning of the meeting, describe briefly:
  
  - b. At the end of the meeting, describe briefly:
  
2. How did people react to information over the course of the meeting; verbally, non verbally? Indicate (age/gender/status), who's saying/asking what.
  
3. Which information captured people's attention the most, and which was hardest to understand? Why and in what way and how do you know?
  
4. Which topics if any caused disagreement amongst people attending the meeting and who (which groups/individuals) disagreed, and what was this based on?

### **D. Informal discussions/observations**

1. **Pre meeting:**
  - a. KEMRI/CDC
  
  
  - b. Community members attending the meeting
  
2. **Post meeting**
  - a. KEMRI/CDC
  
  
  - b. Community members attending the meeting

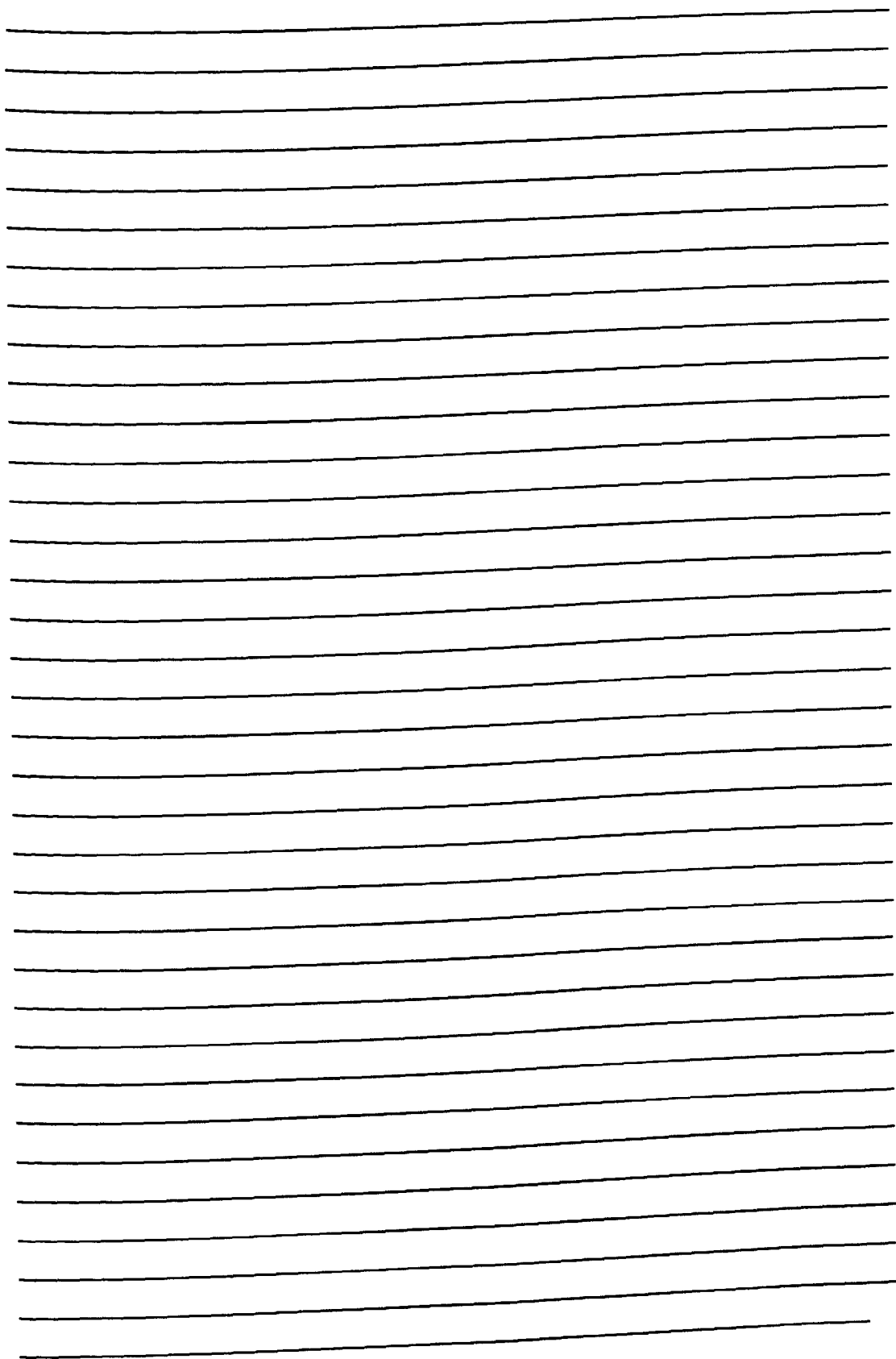
**List of Specific Questions asked about MAL 55 (RTSS Phase 3) and ROTA**

Questions	At what stage	What, who, why?	Response from team; verbal/non-verbal	Pending/follow-up issues

**Continued: List of Specific Questions asked about MAL 55 (RTSS Phase 3) and ROTA**

Questions	At what stage	What, who, why?	Response from team; verbal/non-verbal	Pending/follow-up issues







**OBSERVATION TOOL: Malaria Vaccine Trial Consent Processes**

**Information for the field worker/staff member administrating consent:**

**Designation of person obtaining consent:** \_\_\_\_\_

**Health Facility:** \_\_\_\_\_

**Venue of consent process:** \_\_\_\_\_

**Stage of Participant Flow:** \_\_\_\_\_

**Someone present with the mother:** YES/ NO      **Who:** \_\_\_\_\_

**Was parent asked if they would like anyone else to be present during the consent process?**

YES/NO

**Were parents asked which language they would like to use in consent?** YES/NO

**What did they say?**

**Language used in consent:**      Kiswahili      English      Dholuo      Kigiriama

**Child ID:**

**Age of child at consent:**      6-13 weeks      5-17 months

**Parent's locator details:**      Division \_\_\_\_\_      Sub-location: \_\_\_\_\_

**Time consent started:** \_\_\_\_\_ **Time consent ended:** \_\_\_\_\_ **Total:** \_\_\_\_\_

**Explanation of signature given:**      YES/NO

**Independent witness present:**      YES/NO

**Had they already been given the opportunity to read the consent form?** YES/NO

**Were they given the opportunity to consider the consent form over a longer time period?**

YES/NO

**Details:** \_\_\_\_\_

**If yes, when, where, for how long?** \_\_\_\_\_

**During consent process was the ICF read in its entirety:**      YES/NO

How interactive was the session, i.e. were questions encouraged as ICF read:

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Disturbances during consent process: YES/NO

If yes, what disturbances:

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Questions raised by parent/guardian or other person during consent process:

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How were these responded to?

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Were minimum requirements of consent form covered, if the form was just summarised?

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---

WHAT ARE THE BASIC requirements? Find out from Chris, Mary, Kilifi staff.

Other information gathered informally during the consent process (for example):

How found out about the study: \_\_\_\_\_

Have they read study material in advance: YES/NO

If yes, what kind of material: \_\_\_\_\_

## **Appendix I, Document 7:**

**RSTMH Biennial Meeting 8<sup>th</sup>-10<sup>th</sup> September 2010**

### **Abstract of an Oral Presentation:**

#### ***'We can't involve everyone': A Comparative Case study of Community Engagement Processes at two Malaria Vaccine Trial Sites in Kenya***

##### **Purpose of the research**

This case study compares the practice of community engagement (CE) across two malaria vaccine trial sites in Kenya. Researchers based at international collaborative research centres in Kilifi and Kisumu are investigators in a multi-centre efficacy trial of the RTS,S vaccine. Drawing on ethnographic field work from both sites we share and discuss the implications of experiences gained while engaging the 'community' before and during the RTS,S trial.

##### **Principal results**

Both sites developed a diverse range of CE activities, which together emphasised communication and local representation. A difference between the sites was the involvement of a community based advisory board in the Kisumu site and a research based advisory group in Kilifi. In practice challenges have arisen in both sites concerning; who the key communities are, the selection of representatives, cooperation between parties, and the remit and understanding of community involvement.

##### **Major conclusion**

It is argued that a systematic approach to CE can help ensure that communities are not used as means to an end in international research. Our experience suggests that transparent goals, flexibility and responsiveness to the local context are also essential to develop and sustain relationships which are the cornerstone of collaborative research.

**Author: Malaria Vaccine Trials Community Engagement Research Group\***

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## **Appendix II: Research Findings**

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### **List of Documents**

1. Big Issue Article
2. KEMRI/CDC Standard Operating Procedure: Community Engagement and Mobilization
3. KEMRI/CDC Standard Operating Procedure No. 11: Village Reporters
4. Newsletter for the KEMRI/CDC Community: Dound Oganda (Voice of the People)
5. Appointment Letter for a CAB member
6. CAB Training Materials
7. Chiefs' Charter of Service
17. Malaria Vaccine Trial Power-point Presentation
18. Memorandum of Understanding Between SDH and KEMRI/CDC

## **Appendix II, Document 1:**

### **Big Issue Article:**

**'Rarieda Guinea Pigs insist they were tricked into joining the study'**

# Rarieda guinea pigs insist they were tricked into joining study

By Big Issue Team

**E**VEN as Dr James Nyikal, the Director of Medical Services was last Friday writing a Press statement to deny any impropriety in the way medical research is being carried out in Rarieda, bizarre stories of apparent unethical practices were being told by alleged victims.

Last month, Dr Nyikal and Health Minister Charity Njiru had promised an investigation into the "guinea pigs of Rarieda", shortly after we published the exposé on December 22, 2003.

It is apparent, however, that no investigation has been carried out to ascertain the validity or otherwise of the claims by villagers that they are being subjected to unethical research practices.

Last week, recruits to the study still insisted that they had been lured into the research with promises of free food and financial benefits, while not being told the real implications of their participation.

While a number confirmed, as is apparent in the testimonials below, that they signed no consent forms to enter the experiments, which initially involved trials for a malaria drug, Malorone, and later antiretrovirals.

Other than a letter by A Dr Steven Andersen thanking the recruits for volunteering to take part, most of them deny signing any papers.

But later, after issuing the statement, Dr Nyikal noted: "There may be an issue here, insofar as the villagers are concerned. But if you want to investigate, we will give you all the necessary assistance. It could take quite a while, but you will establish the truth."

But last week, recruits, who believe they were tricked into taking part, say no one has visited to investigate their claims.

Below are excerpts from those *The Big Issue* interviewed.

## Lucas Oyombe Otieno, 44

On May 16, 1996, a team of researchers from Walter Reed, a research unit of the American Army, then based at Kasitu in Kisumu District, visited my village. Their mission was to design a malaria prevention study on Malorone. The study was to take two months. According to a letter dated May 11, 1996, and signed by a Dr Stephen Anderson on behalf of the study team,

those who chose to participate in the project were required to visit their nearest drug distribution centre every day, including holidays and weekends, until the end of the trials.

Earlier, the survey had been done in several villages within the division, and according to the scientists, malaria was identified as a common problem.

The researchers soon started recruitment, where several people most of whom were women from the village, were hired as field workers.

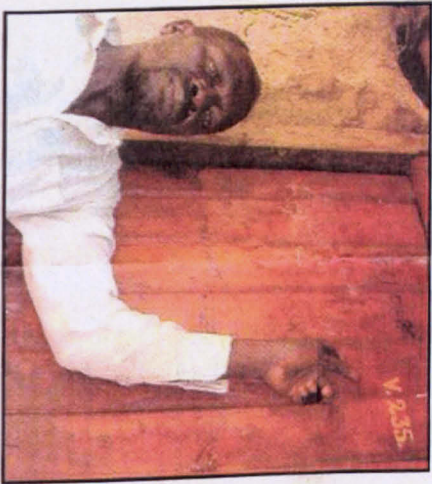
The workers' first assignment was to persuade as many people as possible to take part in the study.

The researchers promised a list of good things to the locals, such as free treatment against malaria to those who volunteered for the study. They also pledged to give food throughout the study period. The volunteers were also promised financial assistance, which they were told would come after the completion of the trials.

These pledges lured many of the residents, who eventually accepted to be used in the study, but were largely ignorant of the possible side effects. Upon taking the drugs on the first day, I noticed a strange thing. But soon after eating, I went home. Later that evening my ears suddenly blocked and I was unable to hear. My eyes began itching.

The following day, I visited fellow villagers who, surprisingly, had experienced the same thing. Instead of complaining to the researchers, we resolved to stop using the drugs.

However, we continued to visit the distribution centre at 11 work and received the drugs so as to enjoy the free meals. We would collect



Soda pointing at a marked door.



Oyombe showing his study ID.

PICTURES: TITUS MUKULA



Otieno



USAMRU-K

UNITED STATES AID FOR DEVELOPMENT

RESEARCH STUDY

Some of the volunteers were not as coming and would throw them away later.

Not that it was anything spectacular we are used to receiving such visitors here. In the past 20 years, two of

**Appendix II, Document 2:**

**KEMRI/CDC Standard Operating Procedure: Community Engagement and  
Mobilization**





# KEMRI/CDC

## Research and Public Health Collaboration

<h3>Standard Operating Procedure</h3> <p>COMMUNITY ENGAGEMENT AND MOBILIZATION</p>	SOP No: 1000-LIA-001 Supersedes: N/A Version: 00 Effective Date: 15 OCT 2010 No. of pages: 1 to 6
--	---

Branch	Base
Section	Community Liaison

	Name	Signature	Date of signature
Author	Ben Okoth	[Redacted]	11 OCT 2010
QA Reviewer	Daveline Nyakundi	[Redacted]	04 OCT 2010
Approval Authority	Dr Kayla Laserson	[Redacted]	15 OCT 2010



**1. PURPOSE/ APPLICABILITY**

- 1.1. **Purpose:** This document is available to be used by projects/studies during community entry and exit process.
- 1.1. **Applicability:** this procedure applies to all studies within KEMRI/CDC Research and Public Health Collaboration

**2. SUMMARY**

- 2.1. NA

**3. ABBREVIATIONS AND TERMS:**

- 3.1. CDC                      Centers for Disease Control and Prevention
- 3.2. KEMRI                  Kenya Medical Research Institute
- 3.3. DO                        District Officer
- 3.4. DC                        District Commissioner
- 3.5. CAB                      Community Advisory Board
- 3.6. CLO                      Community Liaison Officer
- 3.7. MOH                     Medical officer of Health
- 3.8. VR                        Village Reporter

**4. EQUIPMENT AND MATERIALS:**

- 4.1. N/A

**5. RESPONSIBILITIES:**

- 5.1. It is the responsibility of the CLO to generate community support and acceptance for KEMRI / CDC activities and to mobilize the community for informed participation by following this SOP.
- 5.2. It is the responsibility of the respective study or project to contact the community liaison office when the need community mobilization services in good time

**6. PROCEDURES:**

- 6.1. Entry into the community requires the establishment of ongoing partnerships with key respected persons who represent the needs, concerns and wishes of the targeted community. These stakeholders may include:

- 6.1.1. Members of the community ,
- 6.1.2. Youth groups,
- 6.1.3. Women's' groups,
- 6.1.4. Teachers, social workers,
- 6.1.5. Local community leaders (chiefs, assistant chiefs and councilors),
- 6.1.6. The District Officers, the District Commissioner,

- 6.1.7. The District and Municipal Medical Officers of Health,
  - 6.1.8. Religious leaders,
  - 6.1.9. Farmers,
  - 6.1.10. Formal and informal work-based groups,
  - 6.1.11. The local medical community,
  - 6.1.12. CDCs research staff and research scientists of KEMRI and CDC.
- 6.2. Continued dialogue with provincial administration, local community leaders, opinion leaders, and existing networks of representatives of key community groups is important to maintain community engagement prior to and during the course of the study.
- 6.3. Establishing a community advisory board (CAB).
- 6.3.1. Stakeholders from the community are identified to serve on the CAB using a community-driven nomination approach. It involves representatives of community groups or organizations proposing individuals to be selected for the CAB.
  - 6.3.2. The CAB functions as the primary link between the community and the study research team.
  - 6.3.3. The CAB meets on a regular monthly or as-needed basis to support study recruitment
- 6.4. Study recruitment is supported by the CAB through:
- 6.4.1. Disseminating information about the study,
  - 6.4.2. Providing feedback on community acceptance,
  - 6.4.3. Advising staff on participant recruitment strategy
  - 6.4.4. , Providing an additional safeguard for participants' rights,
  - 6.4.5. Providing representation at community meetings.
- 6.5. Meetings and discussions about the study and how to promote community awareness is organized with key categories of community members which may include local community leaders, school heads, youth, religious leaders, women's groups and opinion leaders.
- 6.6. The CLO or designee introduces the prospective Research Community to the study; goes over details that may include:

6.6.1. Goals and objectives of the study to the target community;

6.6.2. Concepts and requirements important to a specific study.

6.6.3. Voluntary participation.

6.6.4. Importance of follow-up

6.6.5. Precaution on use of biomedical intervention.

6.6.6. Possible risks and benefits.

6.6.7. Confidentiality.

6.7. These meetings occur before, during and after recruitment is closed.

6.8. Meetings provide a forum for ongoing dialogue between KEMRI/CDC and the community regarding study-related information, feedback and concerns. Questions and concerns are to be addressed adequately.

**Channels to Use for Community Entry and preparations for KEMRI/ CDC studies**

PROVINCIAL ADMINISTRATION	MOH and OTHER PARTNERS	GENERAL PUBLIC	
District Commissioner Provincial Commissioner DDO DDC Chiefs Assistant Chiefs Village Elders IECs materials Meetings and Barazas DOs	<ul style="list-style-type: none"> <li>• Health Facility Management Teams</li> <li>• DHMT (Monthly Meetings)</li> <li>• District Director of Public Health</li> <li>• District Director of Medical Services</li> <li>• Provincial Director of Public Health</li> <li>• Provincial Director of Medical Services</li> <li>• NGO's and CBO's (through NGO and CBO forums)</li> </ul>	<ul style="list-style-type: none"> <li>• Schools</li> <li>• Churches</li> <li>• VR's</li> <li>• Women groups</li> <li>• Youth Groups</li> <li>• Men Groups</li> <li>• Other Organized Groups</li> <li>• Boda Boda riders</li> </ul>	<ul style="list-style-type: none"> <li>• CAB members</li> <li>• Touts</li> <li>• Political Leaders (Councillors/MPs)</li> <li>• Media</li> <li>• IECs</li> <li>• Chiefs</li> <li>Market Places</li> </ul>

**Activities involving all these stakeholders culminate to a launch**

7. QUALITY CONTROL:

7.1. From time to time both the CLO and individual studies/projects evaluate the effectiveness of this process both directly and indirectly.

8. DOCUMENT CONTROL SECTION:

8.1. Document Control Log

DATE PRINTED: 15 OCT 2010		NUMBER OF COPIES: 6	
SOP DISTRIBUTION			
HDSS BRANCH	GAP BRANCH		
MALARIA BRANCH	BASE ADMINISTRATION		
TB BRANCH	IEIP BRANCH		
HIVR BRANCH	INTRANET		

9. Version history

Version Control Table

Status	Date	SOP No	Version	Pages
ORIGINAL	15 OCT 2010	1000-LIA-001	00	5

10. REFERENCES:

10.1. N/A

11. APPENDICES:

11.1. Forms

11.1.1. N/A

11.2. Attachment

11.2.1. N/A

## **Appendix II, Document 3:**

### **KEMRI/CDC Standard Operating Procedure No. 11: Village Reporters**

## **VILLAGE REPORTERS**

**Standard Operating Procedure 11, Version 1<sup>st</sup> November 2011**

### **DEFINITION**

A Village Reporter (VR) is an individual selected by the community members at village level after meeting specified criteria, to support the implementation of KEMRI/CDC projects and studies. This individual is the interface between the community and the CDC/KEMRI staff. The VR supports all CDC/KEMRI projects in the designated geographic area. The support offered by VR's is an essential and valued component to the success of our work. The village reporters are not CDC permanent employees. They are engaged by projects on a need basis.

### **What are the specified hiring criteria for VR's?**

The VRs are selected by members of a village in a community –driven election process. They should meet the following criteria.

- Be respected members of the community.
- Able to read and write.
- Having basic knowledge in public health.
- Willing and ready to work

### **Key duties and Responsibilities**

- Assist in mobilizing the community at all levels through barazas and other community events.
- Capture data on births and deaths for HDSS. Report this data to vital events supervisor on a regular basis.
- Participate in trainings on new projects. Once trained, the VR's will support the education and awareness efforts of the project at the village level.
- Identify key opinion leaders for KEMRI/CDC who may be interested in serving on the local Community Advisory Board (CAB).
- Assist in identification of village boundaries for HDSS mapping.
- Provide any required information to the study teams during the community entry stage for projects; e.g. identification of compounds, cultural practices etc.
- Share village schedule with study teams so that knowledge of key cultural, life stage and market days are known.

- Encourage community members to utilize available public health services provided by KEMRI/ CDC i.e. HIV/AIDS services.
- Participate in basic health education training to members of the community.
- Introduce project staff to the community through visits to barazas, households and compounds.
- Capture community concerns, suggestions and compliments about the KEMRI/CDC and report the same to the liaison officer for onward transmission to KEMRI / CDC management.
- Projects intending to use the VRs should complete the Village Reporter Request Form at least one week in advance and forward to the Community Liaison Officer. The CLO will then identify the VR and avail the same to the User project. The form is available on the Intranet. Please specify the study area (Gem, Asembo or Karemo) the village/villages, the number of VR's required, and date and time needed.
- For the scheduled VRs meetings, e.g. HDSS weekly meetings the VRs will be paid the daily rate of Kenyan shillings (Ksh) 350.
- The VRs will be entitled to Ksh 250 shillings transport allowance to pay for bus fare to collect money at the bank. The 250 shillings is transport allowance not transport reimbursement.
- Project field officers are responsible for completing VR time cards stating clearly the type of work conducted by the VR and the hours worked. Ensure that the VR and the Project Officer are in agreement on the hours worked.
- Two separate projects are at liberty to utilize the services of one VR in one day provided the hours of usage don't overlap.
- In the case when a VR is utilized by two projects in one day; e.g. TBOR uses a VR from 8.00am to 10.00 am and DSS uses the services of the same VR from 1.00pm to 5.00pm, the VR will be paid a daily rate of Ksh 350.
- HDSS Vital Events Supervisors will collect all time cards and submit them to the Community Liaison Officer (CLO).and the HDSS Field supervisor, the two will then peruse the forms to confirm that the entries are correct. The CLO will then take the forms and forward to finance office for processing. All time cards must be submitted to the CLO by the 20<sup>th</sup> of every month for processing.

**Appendix II, Document 4:**

**Newsletter for the KEMRI/CDC Community: Dound Oganda (Voice of the People)**



# Duond Oganda

A Newsletter for the KEMRI/CDC Community

Volume 2 Issue 1

## Rotavirus Vaccine proves to be effective in preventing severe disease within the first year of life

After over two years of research and follow-up, KEMRI/CDC has proven that the rotavirus vaccine known as RotaTeq™ can effectively prevent severe diarrhea caused by rotavirus by 82% within the first year of life.

Results of this incredible study were disseminated to the participating communities in the month of January.

Hundreds of mothers and their children who took part in the study, community leaders and other stakeholders turned up at the dissemination centers of Ng'iya Primary School, Ting' Wang'i, Bar Olenko and at the Siaya Villa Hotel.

A total of 1,308 children were enrolled into the study which began in Karemo division, Siaya District. 656 children received the vaccine and 652 the placebo. Out of these there were 82% fewer cases of severe

rotavirus diarrhea in the first year of life for those who got the vaccine.

Rotavirus is a virus that causes severe diarrhea among infants and children throughout the world leading to between 600,000 and 870,000 deaths of children each year, especially in Africa.

KEMRI/CDC Field station Director, Dr. Kayla Laserson who has been leading a team from KEMRI/CDC in the dissemination exercise lauded the vaccine trial and the subsequent results.

If all goes well, the vaccine may be in the market within the next three years to help save the lives of the thousands of children in Africa and the entire world.

## Teenage Girls Benefit from KEMRI/CDC Donation

For many young girls, growing up is a process that is loved and embraced. However, for most of those girls in Nyanza, especially for those from poor families, growing up can be a scary process. One aspect of growing up is a girl's menstrual period. Many young girls from poor families cannot afford sanitary pads and therefore become very distressed and some have to miss school.

In a bid to assist young girls in this situation, the Kenya Medical Research Institute and Centre for Disease Control Research and Public Health Collaboration (KEMRI/CDC) set aside about Ksh 360,000 for the purchase of sanitary pads.

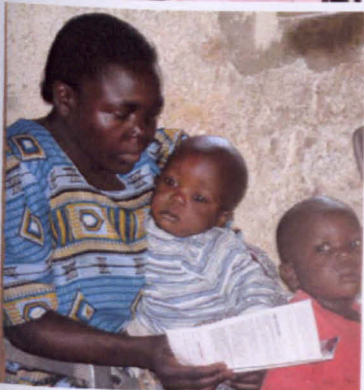
The sanitary pads were meant to assist 1000 young girls in primary schools who are just beginning their menstrual periods for one year thus reducing the level of absenteeism in

school among these girls. The pads will be distributed in Kisumu, Rarieda and Siaya districts.

According to the World Bank, if a girl misses 4 days of school every 4 weeks due to her menstrual period, she will miss 10 to 20 percent of her school days.

The first batch of the essential item was handed over at Ezra Gumbe Primary School at a ceremony presided over by the Deputy Research Station Director Rebecca Lee Pethel and Kisian Primary School both in Kisumu.

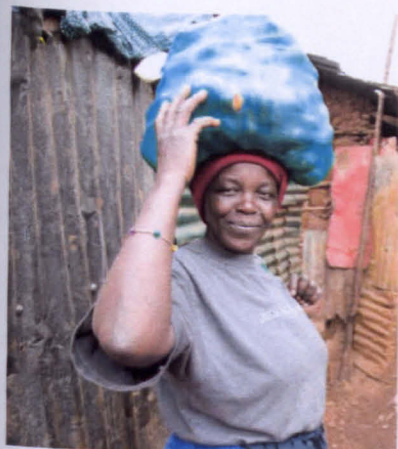
146 boxes were donated to the Mission for Africa in Mamboleo, Kisumu. 87 boxes with about 1500 pieces were distributed among the three KEMRI/CDC study areas of Karemo, Asembo and Siaya.



**Top:** CDC employee, Daveline Nyakundi shares results with a participant; **Above:** A mother and a child who were part of the study. **Below:** Girls show off sanitary pads provided by KEMRI/CDC to them



## Hope for Pregnant Women as KEMRI/CDC Prepares to Begin Drug Trial



The Head of Epidemiology in the malaria Branch, Dr. Peter Ouma, said preparations for the Mefloquine (MQ) study have been done and the study has begun.

He said that the evaluation would be done in five African countries including Benin, Gabon, Tanzania and Mozambique through the Malaria in Pregnancy (MIP) consortium; a five year program to evaluate new and improved interventions for the prevention and treatment of malaria in pregnancy. KEMRI/CDC is a member of MIP. Other collaborating partners are the Bill and Melinda Gates Foundation and the Vienna School of Clinical Research (VSCR) in Austria.

Malaria affects approximately 50 million pregnancies every year, most of them in Africa. Many pregnant women in Africa are infected with HIV which increases the

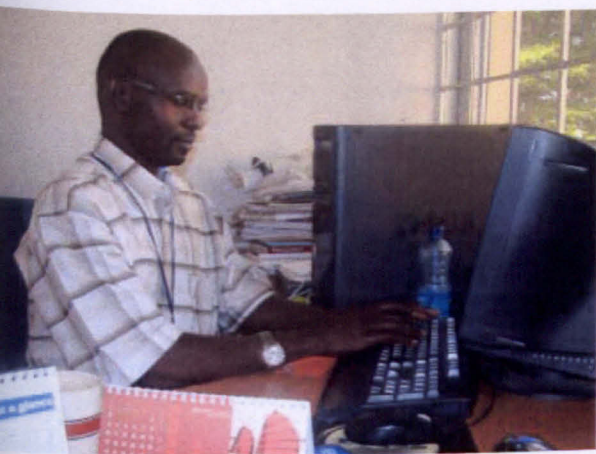
susceptibility to malaria.

This therefore means that current malaria interventions may not work properly. MQ has been endorsed by researchers as one of the most promising drugs to be used by HIV infected women.

During the study, two trials will be done at the same time, one in Benin, and Gabon which represents countries with low HIV prevalence (HIV-negative women only) and in Kenya, Tanzania and Mozambique representing HIV-positive pregnant women and will last for about 30 months.

KEMRI/CDC is soon beginning a study to assess the benefit of Mefloquine (a drug against malaria) for prevention among HIV-infected pregnant women, who are currently taking daily seprtrin dose.

## Long-serving Employee Making a difference in Home Area



Project through the request of the then head of Entomology Dr. Ray Beach. When he joined KEMRI/CDC, the staff population was less than 20 people.

Since joining KEMRI/CDC, Olang has steadily risen through the ranks to his current position of Deputy Entomology Chief. In 1999 he was promoted to the position of a Deputy

Field Supervisor. A position he held till 2003, when he was promoted to his current office.

In his 19 year stint, Olang has been a beneficiary of a four month CDC Atlanta-

funded training in Epidemiology with the University of Emory in the USA in 2001. The training brought together CDC staff working on malaria from 20 countries.

George was born and lives in Korando B Sub location - where the Kisian KEMRI Centre is located - in Central Kisumu location of Kisumu West District and is married with three boys.

He is proud to be part of KEMRI/CDC which is making a difference in his own community. What is George's key to success? "Hard work, commitment and determination and inculcating a culture of trust between you and the employer is the key to success."

George Olang (47), the Deputy chief of the Entomology Department is undoubtedly one of the longest serving members of staff at KEMRI/CDC. 19 years ago, he joined the organization as a Field Assistant after serving a year at KEMRI/Walter Reed

**Geno ne mine ma yach ka KEMRI/CDC chako nonro mar yath/yien.**



Jatelo mar migao mar nono tuoche (epidemiology) e kambi mar KEMRI/CDC Peter Ouma ne owacho ni nonro ibiro tim e pinje a bich kaka Kenya, Benin, Gabon, Tanzania kod Mozambique. Nonro enokau higni abich e bwo riuruok mar Malaria In Pregnancy (MIP) Consortium.

KEMRI/CDC en ja kanyo mar ruirogni. Kaluore kod Ouma, nonro ni ne one ni ber nikech tuo mar Malaria masani koro mako mine chiegni Million 50 ma yach higa ka higa, kendo thothgi yudore ei Africa ka.

Olero bende ni mang'eny kuom mine ma yach ei Africa ni kod kute mag ayaki ma bende miyo Malaria mako gi mayot ahinya. Mae osemiyo obet tich matek ahinya kaka inyalo geng' tuo mar Malaria ka itiyi kod yedhe ma owinjore nikechyedhe ma indilo ne ayaki samoro okwinjre kod yedhe mag Malaria e yo makare.

Yien mar Mefloquin osepwodhi kod jolony

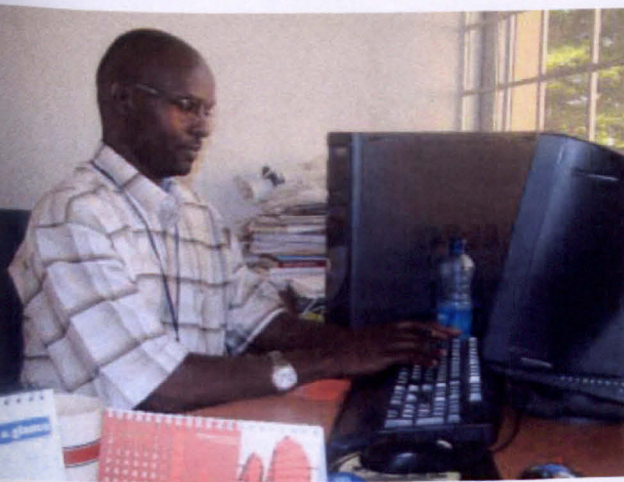
kaka yath manyalo tiyo makare kuom geng'o tuo mar Malaria kuom mine man kod kute mag ayaki. Bende oseyudore ni onge hinyruok mawuok bang tiyo kod MQ epinje Africa, mae miyo en e okang' ma malo ka ipime kod yedhe mamoko. Bende wachore ni ober ka mine ma yach otioy kode ka gidhi wuoth.

E ndalo mag nonro, ibiro teme nyatieng' ariyo, mokwongo ibiro tim e pinje mag Benin kod Gabon kuom mine ma yach to onge kute mag ayaki.

Machielo enotim Kenya, Tanzania kod Mozambique kuom mine ma yach kendo ni kod kute mag ayaki. Nonro duto biro kawo kinde mar dweche 30.

Nonro ewi ber mar yath/yien mar Mefloquin (MQ) kaka rageng' mar Malaria kuom mine ma yach to ndilo Septrin to kendo ni kod kute mag ayaki osechak kod KEMRI/CDC ka giriwre gi jo kanyo mamoko ei Africa.

**Jatich ma Osetiyo Aming'a kelo Lokruok e Gweng'e**



CDC. Ne ochako 1990 kaka jakony weche mag pap bang tiyo kuom higa achiel e kambi mar KEMRI/Walter Reed ka ne oywaye kod Dr. Ray Beach mane otelo ne Entomology ndalogo.

Ne ochako ka KEMRI/CDC ni kod jotich matin ne 20 kende. Nyaka ne odonj

CDC Olang oseidho ngas nyaka koro kama entie kawuono. 1999 ne othule malo ma oyiere kaka jalup ogai mar jotij pap. 2003, ne ochak othule nyaka a fise ma sani.

E hike mar 19 sani, higa mar 2001 ne oyudo thuolo mar dhi somo kuom dweche ang'wen e piny USA ka ichudo ne kod CDC Atlanta to kod Mbalariany mar Emory kama ne osomoe Epidemiology.

Somo no bende ne oyworie koda jotij kidienje mag malaria koa e pinje 20 ma CDC nitiere. Higa mar 2007 ne otimo Diploma e weche mag tayo project.

Olang en ja gweng' ma Korando B Sublocation, Central Kisumu Location ei Kisumu West District. En kod min ot kendo Nyasaye osegwedhe kod yawuoyi adek ma sani ditro.

Olang mor kendo opwoyo tije KEMRI/CDC egweng'e kod mier mamoko. Mogik to owacho niya, " Onge tich maber kata marach. Jatich nyaka ti matek, bed kod luoro kendo chanre maber."

Olang kod higni 47, en Jalup jatelo mar migao mar Entomology kendo en achiel uom jogo ma osetiyo kuom kinde nathothie molojo e riuruok mar KEMRI/



# Duond Oganda

A Newsletter for the KEMRI/CDC Community

Volume 2 Issue 1

## Chanjo mar Tuo Diep Osefwenyore ni Geng' o Tuo e Hik Nyathi Mkwongo.

Higa ni mar 2010, migao mar KEMRI/CDC nyocha osudo mbele e tije mar timo nonro kod tiyo kanyakla ne ngima mar oganda, bang' golo ayanga dwoko mag nonro mar chanjo mar tuo mar Rotavirus. Dwoko ne ogol ayanga ne ogendni mane nitie e nonro.

Mon kod nyithindgi mane jokanyo mag nonro ne ochopo kar rommgi kaa achiel kod jotelo mag Oganda kod ji mamoko e kwonde mane obagie budho kaka Ng'ya Primary, Ting' Wang'i, Bar Olengo to kod magawa mar Siaya Villa.

E nonro ni, nyithindo 656 ne oyudo chanjo mar Rotavirus ka mamoko 652 ne oyudo ma iluongo ni placebo. Duto ne gin nyithindo 1059. Nonro ne onyiso ni chanjo ne otiyo maber marom 82% ei higa mkwongo mar nyathi, tiendeni tuo mar diep mar Rotavirus ne odok piny kuom 82% kuom nyithindo mane oyudo chanjo.

Tuo diep mar Rota kelo diep manyalo neko ne nyithindo makwar kod madito e piny ngima kendo okelo tho ne nyithindo ma kwandgi ni e kind 600,000 kod 870,000 higa ka higa moloyo to e piny Africa. Nonro mar chanjo ne ochaki ayanga Siaya district higa mar 2007.

Jatelo maduong' e Field Station mar KEMRI/CDC Ajuoga Kayla Laserson ma bende ne otelo ne jotich mag KEMRI/CDC e golo ayanga duoko mar nonro, nyocha mor ahinya kaluore kod nonro kod duoko mar nonro owuon. En geno mar ji duto ni ka chenro obet kaka onego, to dip o ka chanjo mar Rotavirus oketi kaka yor thieht kata geng' o tuo ma nego nyithindo tieko ei Africa kod piny ngima.

## Nyiri ma Dito Oyudo Kony koa kuom KEMRI/CDC

Ne nyithindo mathoth ma nyiri, migepe mag dongo gin kinde ma oher kendo ogen ahinya. Kata kamano, mang'eny kuom nyiri gi ma ae anyuola mar jochan dongo kod pek ahinya. Ne thoth nyiri e kor gwenge ma Kenya, migao mar dhi e dwe nyalo bedo mar wich kuot, moloyo to ka nyako onge kod taulo ma mon tiyo go ka gidhi e dwe (sanitary pads).

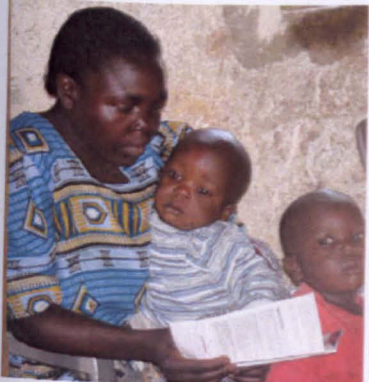
Nikech dhier, nyiri mang'eny ok nyal nyiewo gige kony kendo nikech wich kuot, chuno gi mondo kik gidhi e skul nyaka dwe rum.

Kaka achiel kuom yore mag chiwo kony, migao mar KEMRI/CDC oseketo thenge manyonge maromo 360,000 mar nyiewo taulo ne nyiri matindo ma koka chako dhi e dwe madrom 1000 ma nitie e skunde mag Primary. Taulo gi nochiw e districts mag Kisumu kod Siaya kendo biro duoko piny kwan mar nyiri ma bare ne skul nikech gidhi e dwe.

Kaluore kod nonro mar World Bank, ka nyako obare ne skul kuom ndalo ang'wen e kind jumbe ang'wen nikech odhi e dwe, owito kind 10% gi 20% mag kinde mag somo mage te. Bende osejodore ni thoth nyiri ma bare ne skul nikech dhi e dwe onge kod nyalo mar nyiewo taulo ma ginyalo konyre go.

Nyiri mane okwongo yudo taulo ne omi Ezra Gumbe kod Kisian Primary School e nyasi ma ratipo ka otelie kod Jalup Ja taa tije Rebecca Pethel. Ofuko mamoko 146 ne ochiw ne migao mar Mission for Africa ei Mamboleo, Kisumu. Ofuko mamoko 87 ne ochiw e kwonde nonro mag KEMRI/CDC mag Siaya, Karemo kod Asembo.

Kwonde gi duto, nyiri matinde eka chako dhi e dwe ne nigi mor mokalo kendo ne odwoko erokamano ne KEMRI/CDC. Ne gi mor ni koro ginyalo somo kaka nyithindo mamoko ma ok giluoro dhi e dwe.



**Malo:** Daveline Nyakundi mar CDC nyiso duoko ne ja kanyo mar nonro. **Diere:** Miyo kod nyathine manenie nonro. **Piny:** Nyiri sungo otamba ma KEMRI/CDC ochiwo.



**Appendix II, Document 5:**

**Appointment Letter for a CAB member**



# KENYA MEDICAL RESEARCH INSTITUTE

Centre for Vector Biology and Control Research, P.O. Box 1578 - 40100, KISUMU - Kenya  
Tel: (254) (057) 22923/24 E-mail: cvbcr@kisumumimcom.net Website: www.kemri.org

2<sup>nd</sup> AUGUST, 2007

Dear, Ezekiel Onyango

**RE: APPOINTMENT AS A KEMRI/CDC COMMUNITY ADVISORY BOARD MEMBER FOR KAREMO DIVISION.**

Following your selection by the community and subsequent interview for the position of a Community Advisory Board member (CAB) we are pleased to inform you that you have been offered an appointment with KEMRI/CDC program, studies in Karemo Division.

This appointment is purely **voluntary** and carries with it neither a **salary** nor **benefits**.

I understand that the **MISSION STATEMENT** of the Karemo CAB is

*To foster partnership between KEMRI/CDC research team and the local communities participating in KEMRI/CDC conducted studies to benefit advancement of research and the community.*

And that the **CAB FUNCTIONS** are:

- *They serve as the ears and voice for the community and study participants.*
- *CABs bring specific, unique expertise to the research process, informing researchers of local issues or concerns that can affect the conduct and successful implementation of the scientific agenda.*
- *An active CAB with a committed membership is integral to fostering strong relationships between the community and the research team.*
- *CABs can help strengthen local capacity to respond to critical research needs in the future.*
- *CAB is critical in involving community members at all levels of the research process. A community's participation helps build trust and mutual understanding of research issues and ensures that values and cultural differences among various stakeholders are respected.*

And that I understand my **RESPONSIBILITIES** include:

- *Attend local CAB meetings and provide feedback on issues under discussion.*
- *Voice concerns from the communities and study participants.*
- *Demonstrate commitment to developing an understanding on issues where they may have little expertise and attend workshops.*
- *Assist in the development and implementation of community education activities (health fairs, community forums, etc).*
- *Advise in the development and implementation of recruitment and retention strategies.*
- *Serve as a resource to community liaisons officers and research team.*
- *Disseminate study information to local community.*

**ACCEPTANCE**

I \_\_\_\_\_ certify that I have read and understood my responsibilities, terms and conditions of this offer which I accept/do not accept. I will be available to take the new job by KEMRI/CDC Program with immediate effect.

Signature \_\_\_\_\_ Date \_\_\_\_\_

Sincerely,

DR. Laserson Kayla,  
Director, KEMRI/CDC Research Station.

**Appendix II, Document 6:**

**Community Advisory Board Training Materials**



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## CAB Plan of Action Brainstorming for Friday Meeting at Siaya (23 March 2007)

### Course of Events:

- Tea first (Name tags, (reimbursement, and sign-in sheet)
- Introduction/ Icebreaker (Name tag ice breaker)
- Explain what CDC/KEMRI is and does
- Get a brief overview of the project
- Flipchart---Brainstorm role of CAB...why are you here? (This is not a training but a general introduction and overview)
  - Are you going to do research? Are you going to practice medicine?
  - Explain the role of the CAB
- Create ground rules
- Get advice on the way forward

### Introduction Meeting (Bura nai ng'eruk)

Welcome!!!! We really appreciate your coming to this meeting today and your willingness to participate on the community advisory board for the Rotavirus project. On behalf of the Centers for Disease Control (CDC), Kenya Medical Research Institute (KEMRI), and the whole Rotavirus Project team we would like to congratulate you on being chosen by your community to serve on this advisory board and we want to welcome you to our team. We believe that the community's input is an invaluable part of being successful in this area and we acknowledge that without your support and help it would be impossible for us to conduct good research in this area and to strive towards improving healthcare in the country, which are a few of the main goals of both CDC and KEMRI.

Orwaku, wagoyo erokamano kuom biro maru e bura ni kawono kendo yie maru mondo utiye Community Advisory Board mar nonro mar Rotavirus. Kaka achiel kuom jo CDC, KEMRI, gi ji duto mar nonro mar Rotavirus wamor koyieru gi jogweng' mondo utiye e advisory board kendo waruako u mondo uti kodwa. Wang'eyo ni pach jo gweng' en gima duong' ahinya ee dongruok ma kaa kendo wang'enyoyi ni ka onge siro maru gi kony to ok wanyal timo nonro kaa kata ngero ngima maber e pinywa, ma en achiel kuom dwach jo CDC gi KEMRI.

This is just an introductory meeting and not a training. It will be very interactive, so we will all work as a team. We will be giving trainings at each of the four locations in the very near future. \_\_\_\_\_ If you notice, both members of the first and second CAB are here today and will be asked to attend the trainings. We will explain each of your roles later into today's discussion.

Ma en mana buch ng'eruk kendo ok en mar puonj. Obiro bedo mar woyo omiyo wabiro tiyo kaka ngimoro achiel. Wabiro miyo puonj e location ka location kuom locations angwengo e ndalo mabiro \_\_\_\_\_. Ka unyalo neno, jite maneonyier e Community Advisory Board ni ka kawono kendo ibiro penju mondo

**ubiye e puonj. Wabiro lero ne ng'atoka ngat'to tije bange e woyo mar wa makaa kawono.**

Let us begin! Instead of giving names and introductions, which we would probably forget within a few minutes, we are going to play an introduction game to get to know and feel comfortable with one another.

**Wachakuru! Kar miyo nying gi ng'aruok mabe wich nyalo wil go e dakika matin wabira tugo tuk ng'aruok mondo wang'ere kendo wabed gi thuolo.**

1. Does everyone have a nametag? First, write the name or names that you want the board members to call you by and underneath write the location (not sub-location) that you are representing. Be sure not to show your neighbor what you are writing until the nametag is complete.
  - a. **Be ji te ningi gima, indiko enyinge? Mokwogo ndik nyingi kata nyingengi madiher ni jo board olwongi go, pinyne ndik location (maok sub-location) ma inchung'ne. Neni ok itang'one jabathi ngima indiko nyaka ji te tiek ndiko.**
2. In the top left hand corner answer this question: If you were an animal, what type of animal would you be? Be warned, you will have to explain your answers.
  - a. **Malo kor ka bat acham nduok penjo ni? De in lee kata jamni, lee mane madibedo? Par ni ibiro lero nwa ndowoko mari.**
3. In the top right hand corner write your occupation and what group you represent. You may write midwife, or nurse, or boda boda, or CBO, etc.
  - a. **Malo kor ka bat achich ndik tiji gi migao ma ichung'ne. Inyalo ndiko nyamrerwa jathieth, ja ngware kata CBO kamano kamano.**
4. In the bottom right hand corner write the person that you admire most.
  - a. **Piny kor ka bat achich ndik ng'ama igombo ahinya.**
5. In the bottom left hand corner, write the name of a famous person, alive or dead, that you would like to meet.
  - a. **Piny kor ka bat acham ndik nying ng'ama on g'ere kata kongima kata kaosetho madier romogo.**
6. Now, you have 5 minutes to mingle and find out as much as you can about the other board members and the research team.
  - a. **Koro, un gi dakika abich mondo uriuru uyud mang'eny kaka inyalo kuom ja board moro kata jo nonro.**
7. Now, hand in your nametag and we will mix them up. We will call out some of the things written on each of the nametags and you will all try to guess who the person is. So, be sure to pay attention and get to know one another!

- a. **Koro chiw ngima indike enyingi mondo wariungi. Wabiro wacho ngik moko maondike e gik ndiko e nying moro ka moro. Kendo ubiro temo paro ngatno. Omiyo chik iti mondo wang'ere.**
8. Collect your nametag as you are called out and put it on!
    - a. **Kaw giri mane indikoenyingi ka olwongi kendo irwake.**
  9. ...

Why are we here today? **Ango ma omiyo wan kaa kawono?**

Over the course of the day we will: **Kinde mag odiochieng' wabiro:**

- Get to know members and so that they get to know one another
  - **Ng'eyo jo board mondo wa ng'ere** ✓
- Explain the role of CDC
  - **Lero tij CDC**
- Lay down rules
  - **Keto chike**
- Explain what the role of a CAB is
  - **Lero tij jo CAB**
- Give a very brief overview of the project
  - **Miyo lendo machiek kuom nonro**
- Get advice on how to take the next step (meeting with mothers, fathers, teachers, etc.)
  - **Yudo pachu kaka wabiro kao okang' machielo (romo gi mine, wuone, jopunj gi jomamoko).**
- Give information on the next meetings/trainings
  - **Nyisou mang'eny kuom romo machielo/punj.**

We briefly discussed what the role of CDC is, but we would like to have our ~~CDC Field Station Director~~ to talk to us about the Centers for Disease Control.

**Nwalero matin tij CDC, to dwaher ni CDC Field Station Director onyiswa mang'eny kuom CDC.**

Before we go into matters concerning the Community Advisory Board it is important for you to have a general understanding of the project. We will hand out slides of the protocol or plan for the study. You can look over them while at home and come up with questions or concerns you may have. We will not go into great detail about the study now, but will address all of your questions during the trainings. It is very important that everyone understands the protocol and the study, so that is why we will discuss them in detail in smaller groups during the training.

**Kapok wadhi matut kuom CAB ber mondo ubed gi winjo mar nonro. Wabiro miyou gik mondike chenro mar nonro. Ubiro somo gi dala kendo ubi gi penjo kata ngima dier ng'eyo. Ok wabidhi matut ahinya enonro to wabiro duoko penjou e**

**puoj. Ber kaa ute uwinjo nonro kendo mano emomiyo wabiro lerogi e grube matindo tindo.**

...PowerPoint...

What is a Community Advisory Board and what is your role? You tell us and we'll list your suggestions on the flipchart.

**Community Advisory Board en ang'o, to tiju en ang'o? Nyiswauru to wabiro ndiko pachu.**

- To foster an active and healthy partnership between researchers and local study communities (in this case Karemo Division)
  - **Keto motegno riurwok kind jo nonro gi jo ngweng' (e Karemo Division Ka).**
- The success of the Rotavirus research mission depends upon active participation by the communities involved in the studies.
  - **Ber mar nonro mar Rotavirus ochung' kuom tich motegno mar jogweng' maoriwore gi nonro**
- CABs are responsible for evaluating the impact of the rotavirus study on local communities.
  - **CAB ochung' ne nono duoko mar nonro mar Rotavirus e ngweng'.**
- **They serve as the ears and voice for the community and study participants.**
  - **Gitiyo kaka it gi duol mar jong'weng gi jomanie nonro.**
- **The CAB members will listen to the concerns of the community, with regards to CDC and the research project.**
  - **Jo CAB biro winjo nywak mar jong'weng kaluore gi CDC gi nonro.**
- **They will inform the research team of the concerns.**
  - **Gibiro nyiso jo nonro nywak jo ng'weng'**
- **The members of the CAB and the research team will work together to come up with possible solutions for the problems.**
  - **Jo CAB gi jononro biro tiyo kaka ngimoro achiel mondo giyud yot mar pek moro amora.**
- CABs bring specific, unique expertise to the research process, informing researchers of local issues or concerns that can affect the conduct and successful implementation of the scientific agenda.
  - **CAB kelo rieke maling' ling' e dhi mar nonro, kanginyiso jo nonro pek kata nywak manyalo chando tich kata ber mar chenro mar nonro.**

### Responsibilities of CAB members (Tinj jo CAB)

- **Attend local CAB meetings and provide feedback on issues under discussion.**
  - Biro e buch CAB gi miyo dwoko kuom pek mar jong'weng gi joma ni e nonro
- **Voice concerns from the communities and study participants.**
  - Woyo kuom pek mar jong'weng' gi joma ni e nonro
- Demonstrate commitment to developing an understanding on issues where they may have little expertise; attend workshops.
  - Nyiso chiwruok mari gi dongruok kuom pek manyalo bedo gi nyalo matin; biro e puojruok
- **Serve as a resource to community liaison officers and research team.**
  - Bedo kaka chiw ne jo gweng' gi jo nonro.
- Disseminate study information to local community.
  - Nyiso jongweng weche nonro.
- Each CAB will develop their own mission statement and operating guidelines. It is possible that each group of 6 will come up with their mission statements during training and a general mission statement will be compiled including all of the ideas presented.
  - CAB ka CAB biro yudo ngima, tayogi gi chike. Biro nyalore ni ji auchiel e group ka group biro yudo ngima tayogi saa puonjt bang'e wabiro yudo ngima tayowa kwariwo pachu.

### What will happen in the monthly meetings?

Ang'o mabiro timore e buch dwe ka dwe?

- *The group will meet for an hour prior to research members arriving to compile information heard, rumours, complaints, suggestions, etc.*
- *Jo CAB biro romo saa auchiel kaa jo nonro pok ochopo mondo gi riu gik magiwinjo, gik mawachore/ mawachore, nywak, paro gimamoko.*
- *The CAB will discuss issues with the CDC research team and both will discuss possible solutions and ways forward.*

- *Jo CAB biro wuoyo kuom wechego gi jo nonro mag CDC to gibiro wuoyo kuom gik minyalo tim to gi yudo yore mag dongruok.*

## GROUND RULES

### CHIKE

- Lay down rules. Let us all lay down some rules for this team (brainstorm on flip chart)
  - Keto chike. Watee waketuru chike magwa.
  - One person talks at a time.
    - *Ng'at achiel ka achiel biro wuoyo.*
  - Respect for others opinions/ there is no right or wrong comments.
    - *Luoro pach jomoko/ongge paro maber kata marach*
  - Part of respect includes keeping what is said at these meetings within these meetings. Of course your role is to act as a liaison, but that does not mean that the community needs to know that BRENDA said this or GEORGE said that in the meeting.
    - *Achiel kuom luor en kano ngimoro amora mowach e buche gi. Kata obedo ni tiji en bedo kaka it jogweng' mano ok en ni jongweng' nyaka ng'e ni Brenda kata George nowacho kama e bura.*
  - Active participation/ we would like to hear from each one of you. (Remind them that the community chose them because they are respected. We do not value the opinion of any person over another.)
    - *Tiyo motegno/dwaher winjo kuom ng'ato ka ng'ato kuomu ka (Waparnegi ni jongweng' noyiero gi nikiche oluorgi. Ok wageno pach ng'ato molooyo ng'amachiolo).*
  - Keep time
    - *Rit saa*
  - ATTEND MEETINGS or give notice (*Missing any 3 without informing both the research team and the "substitute" or stand-by CAB member or missing 2 consecutive meetings, whether "excused" or not is cause for disqualification.*)
    - *Bi e buche kata or wach (Koso biro e bura di dek ma ok ioro wach ne jo nonro kata ng'ama ochungni e buch CAB, kata koso biro e bura ndalo ariyo maluore kata omiyi thuolo kata ok omiyi ibiro goli.*
  - (What is a substitute or "standby"?) *Explain*
    - *(Ng'ama ochungni en ng'a?)*
  - The first CAB selected is responsible for attending the meetings in the first year. If there is an emergency and they cannot attend,

the CAB member must first inform the research team and then contact the member of the second CAB that serves as the same role as them to see if they can attend the meeting. That means that everyone here today should be listening to the community throughout the project. After the first year, the second CAB members will be expected to attend all meetings and the first CAB will be on call.

- CAB mokwongo moyier nyaka bi e bura mokwongo e higa. Kanitie ngima ochuno maok inyal biro, ja CAB nyaka nyis jo nonro mokwono bang'e onyis ja CAB mar ariyo matiyo e migao miaye ka nyalo biro e bura. Mano nyiso ni ji tee man ka kawono nyaka chik itgi e ngweng' ndalo tee mag nonro. Bang hig mokwogo, jo CAB mar ariyo biro dwarore ni obi e bura ka jo CAB mokwongo biro chung'negi

Now that we've introduced ourselves, discussed the role of the CAB, and given ground rules we will first open this talk up for questions, then we will ask our first set of advise from you as a group.

Kaa koro wasang'ere, wuonyo ewi tij CAB, miyo chike mokwogo wabiro miyo thuolo ne penjo, bang'e wabiro penjo u yo madutawa ngo.

- After questions we will ask them a question: What is the way forward?
  - Bang penjo wabiro penjo penjo: Walu yo mane?
- Meetings with mothers, fathers, teachers, etc.
  - Romo gi mine, wone, jo puonj, gi jo mamoko
  - (Per area) Where? When? What time?
  - (Location ka location) Kanye? Chieng mane? Saa ndi?
  - Other issues to talk about at these "barazas"
  - Weche moko mawanyalo wuoye "barazas"
  - How do we reach the other mothers/females? How do we reach the people that don't normally attend barazas?
  - Ere kaka wanyalo yudo mine moko? Ere kakawanyalo yudo jogo maok bi e barazas?
  - How do we reach the fathers? When can we get them together?
  - Ere kaka wanyalo yudo wuone? Sadi mawanyalo yudo gi tee
  - How should we organize a teacher's baraza?
  - Ere kaka wanyalo pago baraza mag jopuonje
  - How should we go about general meeting?
  - Ere kaka wanyalo loso buch ji tee.

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- We have listed on the flipcharts the names and contact information of each of the CAB members and which CAB they will serve on.
- **Wasendiko nyingu gi kaka inyal yudu gi CAB ma ibiro tiyo ne.**
- Reminder of trainings and who is on which CAB (Chart of training times and members in each area, including contacts)
- **Paro mar puoj gi CAB mang'ato nitie.**
- Are there any other questions? Again, we look forward to working with you and hope that you will feel completely comfortable with asking any questions or addressing any concerns. Now that we are finished, please be sure to sign the sign-in sheet, collect your transport money and drink a soda.
- **Be nitie penjo moro amora? Kendo wageno tiyo kodu ka paro ni ibiro bedo gi thuolo mar penjo penjo moro amora kata wuoyo kuom pek moro amora. Koro watieko neni iketo lweti eotas manyiso ni ne in ka, kau pesa mar mtoka kato imadh soda.**
- THANKS!
- EROURUKAMANO!



- Study staff will provide certain routine medical services to study participants. This will include free diagnosis and treatment for acute diarrheal illness, upper respiratory illness, malaria and STIs.

## DAY- 2

(Ask four participants to share something new they learned during day 1)



## COMMUNITY ADVISORY BOARDS (CABs) GUIDELINES

### Mission

Community Advisory Boards (CABs) foster partnerships between researchers and local study communities impacted by HIV/AIDS. An active CAB with a committed membership is an integral participant in the effort to combat AIDS. In addition, CABs can help strengthen local capacity to respond to critical research needs in the future.

(KEMRI/CDC)

The success of the HIV-R research mission depends upon active participation by the communities involved in the studies. Including community members at all levels of the research process helps build trust and mutual understanding of research issues and ensures that values and cultural differences among participants are respected.

### Function of the CAB

CABs are responsible for evaluating the impact of HIV-R studies on local communities. They serve as a voice for the community and study participants. CABs bring specific, unique expertise to the research process, informing researchers of local issues or concerns that can affect the conduct and successful implementation of the scientific agenda. Each HIV-R research site will be linked with and support an active CAB.

CAB members may contribute professional or personal experience. For example, CAB members may include health educators, lawyers, school teachers, people living with HIV/AIDS, women of childbearing age, gay and bisexual men, youth, and representatives from the religious community or community-based / non-governmental organizations. CABs provide advice on scientific and ethical

issues regarding study design, recruitment and protection of study volunteers. Each CAB will develop their own mission statement and operating guidelines.

### **CAB member recruitment**

2 CAB members are drawn from the groups above, and through recommendations from leaders in the community, other CAB members, study participants and HIV-R staff. Recruitment is viewed as ongoing, wherein new members are added over time as attrition occurs. All new CAB members will receive an orientation and background materials prior to their first meeting. 1

### **Responsibilities of CAB members**

- 3
- Attend local CAB meetings and provide feedback on issues under discussion.
  - Voice concerns from the communities and study participants.
  - Demonstrate commitment to developing an understanding on issues where they may have little expertise; attend workshops.
  - Assist in the development and implementation of community education activities (health fairs, community forums, media interviews, etc.).
  - Advise in the development and implementation of recruitment and retention strategies.
  - Provide real-life experiences.
  - Serve as a resource to community liaison officer and research team.
  - Disseminate study information to local community.
  - Recruit and orient new CAB members.

### **Suggested CAB operating guidelines**

- The total membership should not exceed 20.
- Membership is open to all members of the community who successfully complete a CAB orientation.
- A CAB should have at least half of the membership regularly participate in CAB activities to be considered "active."
- A CAB member is considered non-active if he/she is absent from three meetings without contacting the CAB liaison.

### **How to build and maintain a successful CAB**

- Timely orientation of new members.
- Clearly stated purpose for CAB involvement.
- Inclusion of CAB members in development of HIV-R research plans.
- Provision of regular training and technical assistance to all CAB members.
- Clearly stated standards, procedures.
- Agreed upon norms and decision-making rules of conduct for the group.
- Provision of administrative assistance.
- Establish means of communication with CAB members.

- Provision of transportation to meetings, conferences, workshops, if needed.
- Skilled facilitation of regular meetings.
- Provision of refreshments.

## WHAT IS CAB?

### DEFINITION

A group of active volunteers from the local community organized to assist and advise the researchers in a given community affected by any form of a problem e.g. HIV/AIDS, TB etc.

### Why Have Community Advisory board? (CAB)

To build a bridge between the community and the research staff, it is important to involve the community in the entire research process. The establishment of community advisory boards will assist the project to develop and execute programs that address the specific needs of the community.

Community participation in the research process can happen in many ways. Sometimes CAB members can be nominated to form a group to advise the research process, as the voice of local questions and concerns throughout a given study.

### CAB Participation in the Research Process;

At a minimum, CAB should be involved in three stages:

#### 1. Before the study

In health-related research, one of the first steps for CAB members is to agree that the research addresses a need or problem relevant to that community and to confirm that the design is sensitive to local norms and culture for example the study should bring some benefits to research participants or the community.

#### 2. during the study;

This is to follow the progress of the study and address any concerns that may arise. As members of the community, CAB members can also be alert to issues or concerns about the research and communicate them to the research staff.

#### 3. After the study,

This should be done after the end of the study mainly to share the findings of the study. Once the research is completed, community representatives can help to make results known and applied to the entire community.

### Activity (10 minutes)

This activity is designed to make participants reflect on their role in the conduct of research.

Ask participants to discuss with a partner for 2 minutes why they think it is important to have community representatives participate in the research process.

Ask each pair to write 2 reasons on a note card. Have participants post these on flip chart paper and tape to a wall. To save time, ask just a few pairs to share aloud with the entire group. Participants can look at the cards more during a break.

### Roles of CAB.

The roles of CAB shall be solely advisory in nature, these includes;

- Serve as the main link between researchers and the community i.e. eyes and ears of the researchers, since, they come from the community and know about it.
- Advise the researchers on study design and implementation.
- Provide important input on how to recruit and retain participants.
- Report any adverse event as a result of the study.
- To alert the research team about rumors

### Terms of Membership

The point of CAB membership is community representation, and therefore it is important that community representatives be as diverse as the study population, fairly representing differences in sex, age and vulnerable groups.

**CAB members should agree to certain terms of membership to serve on a CAB.**

- The role of the board shall be solely advisory in nature.
- Members should regularly attend meetings once in a month or when required.
- Cab membership is strictly voluntary.
- Money for transportation, and other expenses directly related to CAB membership (such as writing materials) should be provided when necessary.
- Study staff should be available to assist the CAB when required and provide the CAB with regular updates and meeting minutes in a timely fashion.
- Residence of the area.
- A responsible member of the community.

### REPORTING FORMAT

Let participants discuss the various ways they think we will be receiving feedback on the happenings in the community and how they will be communicating progress back to their "constituents".

**What happened, where, by whom, is it positive or negative; likelihood to impact on the study; decision taken to arrest situation**

*Discussion of achievements since last reporting*

*Discussion of problems that have arisen.*

*Discussion of work that lies ahead.*

*Assessment of whether you will meet the objectives in the proposed schedule*

**Appendix II, Document 7:**

**Chiefs' Charter of Service**

*[Handwritten scribbles]*



*RAWI ALLO*

**OFFICE OF THE PRESIDENT**

**CHIEFS AND ASSISTANT CHIEFS SERVICE CHARTER  
CITIZENS SERVICE DELIVERY CHARTER**

The chief's office is strongly committed to customer service fairness and impartiality patriotism and loyalty in serving all citizens.

Service	Requirements	User Charges (Kshs)	Time Line
Identification of persons for issuance of Kenya ID cards.	Approval by vetting committees;	Free	1 day
Border Districts	Parents ID cards.	Free	1-24 hours
Other Districts	Recommendation letter from the Asst. Chief. Birth certificate assessment report, Parents ID card, Birth certificate, School certificate or letter of admission. Baptismal card		
Enforcement of the law	Cooperation and support Adherence to the Chief's Act Volunteer information	Free	Within the specific year
Prevent manage and resolve social, political and other conflicts.	Co-operation and participation Factual and truthful information	Free	Continuous Immediate
Detecting and reporting early warnings on disasters and conflicts	Factual information Volunteer information	Free	Immediate/ continuous
Eradicate reported illicit brews, drugs and other substance abuse.	Co-operation and support Disclose brewers, drug peddlers and their strategies	Free	Continuous Continuous
Enable harmonious co-existence of communities	Customers should be committed and cooperative Equitable resource sharing Inter and intra communal social activities	Free	Continuous
Hold interactive public barazas.	Co-operation Feedback reports	Free	At least two barazas per month
Operationalize community policing.	Full participation and cooperation Adherence to community policing policy and citizens handbook	Free	Continuous
Issuance of notification of births and deaths	Medical report/parents' identity card Deceased ID Parents/next of kin's identity card.	Free	1 day
Identification of beneficiaries of deceased persons estates.	Burial certificate of the deceased Birth certificate of beneficiaries Certification of marriage where applicable ID Card of widow/widower	Free	Within 10 days

**"COMMITMENT TO COURTESY AND EXCELLENCE IN SERVICE DELIVERY"**

*In cases where service delivery is perceived to be inefficient or ineffective complaints should be reported to:*

**CORE VALUES**

- Teamwork and partnership
- Transparency and accountability
- Professionalism, Integrity and Excellence
- Innovativeness
- A strong commitment to Customer Service
- Fairness and impartiality
- Patriotism and loyalty

**Contact:**  
Area DO  
Area DC  
Area PC or  
PS 2227414-  
P.O. BOX 30510, NAIROBI

**IT IS YOUR RIGHT TO DEMAND EFFICIENT SERVICE**  
**"Huduma Bora ni Haki Yako"**

**Appendix II, Document 8:**

**Malaria Vaccine Trial Power-point Presentation**



## Malaria Vaccine Study (Mal-055)

KEMRI/CDC, MoH and Other  
Partners



## Why is KEMRI/CDC conducting the Malaria Vaccine study

- We want to test how well the vaccine works in preventing malaria in children
- Malaria is a common disease here in Siaya
- Malaria is also the major cause of severe disease and death in children



## What is Malaria

- A disease resulting from the bite of an infected female anophelene mosquito
- The female anophelene mosquito bites man and then transmits the parasite that causes the infection
- There are 4 species of this parasite:
  - Plasmodium falciparum*
  - Plasmodium vivax*
  - Plasmodium ovale*
  - Plasmodium malariae*
- Of these 4 parasites, *P. falciparum* is the major cause of severe disease and death



## How does malaria affect your community

- In this region, malaria causes the deaths of about 35,000 children every year
- It is a common reason for admission to hospital
- A major reason for school absenteeism and poor school performance
- A major reason of both direct and indirect economic losses



## How do you know if one has Malaria?

- Hotness of the body
- Feeling cold and shaking
- Headache
- Joint and muscle pain
- Sweating
- Vomiting
- Paleness- reduced blood levels in the body
- Damage to vital organs, leading to infection in the brain, liver and lungs.
- If not treated well and early enough, Malaria can progress very rapidly and death may occur within a short timeframe



## What are some of the ways of preventing Malaria?

- Sleeping under an insecticide treated mosquito bednet
- Seeking treatment for Malaria early enough
- Treating Malaria with an effective drug
- Pregnant women taking antimalarial drugs when attending Clinics (ANC)
- Clearing the environment of mosquito breeding places
- Spraying the inside walls of houses with an effective insecticide e.g. in highland areas



### Why is malaria still in the increase

- Poor preventive practices like not sleeping under an insecticide treated bednet, pregnant mothers not seeking care and treatment during pregnancy, poor waste disposal practices etc
- Poor compliance with drugs
- Wrong diagnosis and late treatment
- Increasing Malaria causing parasite resistance to convectional anti-malarial drugs
- Armed conflicts, migration of refugees



### Is this vaccine safe for your child?

- The vaccine has been shown to be safe in children in Mozambique, the Gambia, Tanzania, Ghana, and here in Kenya including in Kisumu
- It is absolutely crucial that the vaccine undergoes a rigorous review and study before a big number of children can receive it



### Why is a vaccine necessary?

- Bednets, spraying, drugs and the other control strategies are important and their use need to be scaled up. However, they are not enough
- The mosquitoes and the Malaria causing parasites are very smart and they learn to resist treatment and now there is constant need to develop new approaches as the Malaria vaccine
- A Malaria vaccine is therefore a very important part of the Malaria control strategy if we are to make a significant gain in the fight against malaria



### How will your child benefit from the Malaria Vaccine study?

- Each child in the malaria vaccine study will receive free outpatient medical care for approximately 3 years
- Your child will also benefit from high level inpatient care should s/he be admitted at Siaya District Hospital
- You will help in an important clinical trial to find ways to prevent malaria in children
- Each child who participates in this study will get an insecticide treated bed net



### Objectives of the study

- To evaluate how well the vaccine is protective against clinical malaria disease caused by Plasmodium falciparum in African male and female infants and children aged
  - 6-12 weeks
  - 5-17 months
    - At first vaccination if they qualify to be in the study.



### Will blood be taken from your child in the study?

- A small amount of blood which is not more than 1/4 tea spoon will be taken five times for the entire duration of the study
- This blood sample will be used to test if your child is well
- Some of this blood will also be used to see if your child's body is developing the strength to resist malaria
- The blood sample will not be used for anything else or to test your child's HIV status



### What bad things can happen to your child if you join the study?

- The malaria Vaccine just like all drugs may have side- effects
- Some children may have mild fever and some discomfort at the vaccine site
- Very rarely a child could have a more severe reaction to the vaccine
- All these reactions are short lived and disappear in a short while



### How many children will be in the study?

- We will seek to enroll approximately 1800 children into the study.
  - 800 children between the ages of 5 – 18 months
  - 1000 children between ages 6 – 13 weeks



### What happens if you don't want your child to participate or you decide to stop being in the Malaria Vaccine study?

- Participation into the Mal-055 study and any of our other studies is completely voluntary. You can refuse to have your child participate in the Malaria Vaccine study at any time. This will not affect you or your child
- If you don't want your child to go on with the study, you can stop at any time



### Where should I go if I have questions about this study?

- Kindly approach a member of the KEMRI/CDC Team here in Siaya at any of the facilities where we conduct studies and they will link you with the appropriate study staff
- Also feel free to contact;
  - Christopher Odera,
  - KEMRI/CDC Research Program,
  - Malaria Branch,
  - P. O. Box 1578-40100,
  - Tel: (057) 2022902,
  - Kisumu.



### Which health facilities can you visit?

- The preparations to conduct the study at an advanced stage and the study may be conducted at;
  - Siaya District Hospital
  - Ng'iya Dispensary
  - Ting'wang'i Health Centre
  - Mulaha Dispensary
  - Kogelo Dispensary
  - Bar Olengo Dispensary
- The final study sites will be communicated to you soon



## Appendix II, Document 9:

**Memorandum of Understanding  
Between  
Kenya Medical Research Institute (KEMRI)/ Centers for Disease Control and Prevention (CDC)  
Program and  
Siaya District Hospital (SDH)**

This MOU serves to demarcate the points of agreement between the Siaya District Hospital (SDH) and the KEMRI/CDC Program, with particular reference to the Demographic Surveillance System (DSS), the Rotavirus Vaccine Trial Project, the University of Maryland GEMS Diarrheal Study, and the TB Cohort Site Preparation Studies. It delineates general guidelines for participating parties and outlines their roles in the various activities. All parties have agreed it is of mutual interest to develop the capacity for operation of successful collaborative studies.

### *Demographic Surveillance System:*

Since 1996, KEMRI/CDC Program and Siaya District Hospital (SDH) have collaborated to collect in-patient surveillance data from children less than 10 years old, at the pediatric ward of SDH. The purpose of this surveillance has been to capture hospital-related clinical and care seeking information from children who reside in the KEMRI/CDC Demographic Surveillance Area (DSS), with a particular focus on malaria. In the past, the DSS area included people living in Asembo and Gem, many of whom sought health care at facilities other than Siaya District Hospital. In early 2007, we expanded our DSS to include Karemo Division. This expansion was done mostly so that we could better capture health-related information on our surveillance participants who attend the Siaya District Hospital. We will expand our operations at the hospital to include child, adolescent, and adult out-patient surveillance, and adolescent/ adult in-patient surveillance. In addition to providing more representative morbidity information, this expansion will allow for surveillance of other infectious diseases of great public health importance in this region in addition to malaria.

### *Rotavirus Vaccine Trial Project:*

Rotavirus is the leading cause of severe diarrhea in infants and young children. This Rotavirus Vaccine Trial, which started July 6 2007, will study the Efficacy, Safety, and Immunogenicity of RotaTeq™ Among Infants in Asia and Africa through a randomized, double-blind (and in-house blind), placebo-controlled trial. RotaTeq™ is an oral pentavalent rotavirus vaccine indicated for the prevention of rotavirus gastroenteritis in infants and children. The trial will continue for approximately 2 years. The enrolled study population for the entire trial will comprise approximately 2000 infants who are between 4 and 12 weeks at the time of enrolment.

### *Global Enterics Multi-center Study (GEMS):*

Diarrhea is a major cause of childhood morbidity and mortality in developing countries. The objective of the study is to estimate the population-based burden, microbiologic etiology and adverse clinical consequences of severe diarrhea among children 0-59 months of age. Seven sites with DSS's and high childhood mortality are participating in this project (Bangladesh, India, Pakistan, Kenya, Mozambique, Gambia and Mali) which is funded by the Bill and Melinda Gates Foundation and administered by the University of Maryland, Baltimore. Patient enrollment will begin in the fall

of 2007 and continue for 3 years. Each site will aim to enrol approximately 220 moderate-to-severe diarrhea patients per year in each of the following three age strata:-0-11months, 12-23 months and 24-59 months. Each site will (a) collect demographic characteristics of their study population, (b) conduct a Health Care Services Utilization and Attitudes Surveys of households containing a child 0-59 months of age at baseline and at the end of the study, and (c) carry out a case-control study of the incidence and etiology of severe diarrhea, and to characterize pathogen-specific risk factors for infection, poor outcome, and mortality. In Kenya, children living in the Asembo and Gem communities under the Demographic Surveillance System will be eligible to participate. Children with severe or moderate diarrhea will be enrolled at several sites where laboratory enhanced surveillance for enteric diseases in children has been conducted for the last 2 years. These include Siaya District Hospital, Bondo District Hospital, Lwak Clinic and Hospital, Ongielo clinic, Akala clinic, Abidha clinic, and Njejera clinic. Additional sites will include Yala Sub-district hospital and Nyawara clinic. The ultimate goal of the study is to provide information needed to guide the development and implementation of enteric vaccines and other public health interventions that can reduce diarrheal disease associated morbidity and mortality.

#### *TB Cohort Studies/TB Vaccine Site Preparation:*

Tuberculosis (TB) has been declared a global health emergency by the World Health Organization (WHO). *Mycobacterium tuberculosis* (Mtb), the primary causative agent of TB, is reportedly responsible for millions new cases of TB and deaths, making it one of the world's most lethal infectious agents and one that causes more adult deaths than any other pathogen. No current vaccine has been shown to reliably prevent pulmonary tuberculosis in adults. The proposed TB Cohort studies will build capacity to conduct phase III TB vaccine trials within Karemo division and will operate from the Siaya District Hospital. As part of these epidemiological studies in neonates and adolescents; we will better document and understand TB prevalence and incidence in these groups while improving active case finding. The studies will run for approximately three years with 2900 neonates and 5000 adolescents recruited into both.

#### **I. Terms of agreement:**

##### *Staff*

The KEMRI/CDC Field Station agrees to supply the necessary staff (both out-patient and in-patient) whose primary responsibility is to conduct all of the KEMRI/CDC studies at Siaya District Hospital. A KEMRI/CDC Primary Investigator may agree to allow its study staff to assist hospital staff in patient care when study procedures allow such an arrangement, after study duties are completed, and as approved by the KEMRI/CDC Primary Investigator. However, the KEMRI/CDC study staff can never be given the sole responsibility for a hospital clinic, department, or health facility, since at any time the KEMRI/CDC staff may be required for study procedures, in which situation a hospital staff has to be immediately available to take over whatever the KEMRI/CDC staff is working on. The Rotavirus Project nursing staff will assist the hospital by administering all KEPI vaccines to study participants. This will allow for a more timely flow of immunization visits and/or allow the MOH nursing staff at SDH to focus on sick visits and other services. Additionally, the Rotavirus Project will provide 3 clinical officers at SDH during the course of this trial (2.5 OPD and 0.5 IPD; this ratio is dependent upon the number of children who are rotavirus participants who are hospitalized). All KEMRI/CDC clinical staff shall wear the proper uniform in the hospital (white coat, closed leather shoes, etc).

The Siaya District Hospital agrees not to release regular Ministry staff because of the presence of KEMRI/CDC study staff.

##### *Medical care for patients*

KEMRI/CDC will not be charged for children < 5 who are seen/managed in the OPD.

The Rotavirus Project will provide full medical care for each participant in the study, including in-patient care for any patient admitted to the IPD while enrolled; for these patients, KEMRI/CDC will facilitate payment of 60 Ksh per in-patient day.

#### *Data*

All data elements collected from out or in-patients at SDH for KEMRI/CDC studies will be shared with the hospital, including results of all lab tests performed by KEMRI/CDC. The KEMRI/CDC program will provide SDH with funds to hire an additional MOH Clinical Officer to assist with DSS related data collection, at the cost of 25,000 Ksh per month; these added personnel/supplements will help to maintain timely patient flow in the out-patient/MCH department. Should SDH remove a regular MOH CO from OPD/MCH, KEMRI/CDC will cease to cover the extra CO costs.

#### *Pharmacy*

Both parties have agreed to share the Pharmacy. Rotavirus Trial participants will access the normal hospital pharmacy for general OPD and IPD formulary needs; KEMRI/CDC will provide study participants with any medications not available. The Rotavirus/KEMRI/CDC formulary can be used for non-Rotavirus trial participants on a case-by-case basis, as approved by the Rotavirus site coordinator and Rotavirus site clinical officer. Specifically, the Rotavirus formulary may be used for severe/emergency cases when appropriate alternative medications are not available in the hospital formulary. In addition, for the vaccine trial(s), the CDC pharmacist will be responsible for ensuring the transport and conditions of the vaccines remain under the standards of good clinical practice.

#### *Space*

KEMRI/CDC will purchase a container to be placed outside the hospital for use by KEMRI/CDC studies. All costs of the container will be borne by the KEMRI/CDC Program. KEMRI/CDC is also embarking upon a large renovation of a clinical and office annex, to be placed next to the hospital. This annex will contain a conference room, clinical and training facilities, and an HIV/AIDS patient support center to be used in collaboration with staff at Siaya District Hospital and the Ministry of Health.

The KEMRI/CDC TB cohort studies will use a room in the pediatric ward as a case verification ward for infants where TB suspects in the neonatal cohort study will be admitted twice a week for sputum inductions, gastric lavage and chest x-rays. During these admissions the study will provide in-patient care, pay for in-patient care costs and provide the staff to care for these infants. Additionally, a TB procedure room will be renovated outside the pediatric ward (space currently used as a laundry area). This will greatly enhance pediatric TB diagnostic capacity at Siaya district hospital.

Siaya District Hospital agrees to allow KEMRI/CDC to have 1 office space (for the Rotavirus Trial) in the maternity ward until the Annex is available. In addition the KEMRI/CDC staff will also continue working from the OPD, MCH and IPD, for all on-going studies.

#### *Monitoring*

Monitoring of the KEMRI/CDC studies is done a regular basis. One or more team members of a particular study, or outside monitors, in the case of our clinical trials, will monitor the quality of the studies and visit the Siaya District Hospital on a regular basis to ensure that medical records, samples, and clinical records are being kept for the study participants and are in order.

#### *Equipment/ Power*

KEMRI/CDC will maintain a specific Rotavirus vaccine refrigerator at SDH. KEMRI/CDC may also provide a small generator as back-up for specific equipment during studies. The KEMRI/CDC Enterics Project owns stand-alone propane powered refrigerators at Siaya DH. KEMRI/CDC Field Station

agrees to pay 21,000 Ksh per month for its share of the shared generator power consumed at the Siaya District Hospital.

*Reimbursements*

All reimbursements will be made with 60 days of receipt of the invoice from Siaya District Hospital. Siaya District Hospital will provide the necessary documentation that the Hospital is only reimbursed for out-patient or in-patient costs related to patients enrolled in KEMRI/CDC studies, and as previously agreed. All charges will be adequately labeled.

**II. General provisions:**

1. This MOU is not intended to, and does not, and may not be relied upon to create a right or benefit, substantive or procedural, enforceable by law by either party against the United States.
2. Monthly meetings will be conducted between both parties throughout the course of the studies; however during the initial stages of the study, it may be necessary to have more frequent meetings. Additional reports will be provided by both parties to discuss the agreements and any changes needed.
3. This agreement may be modified upon agreement by both parties.
4. This agreement may be terminated by either party upon 30 days notice.
5. The Principal KEMRI/CDC contact for this MOU is Dr. K. Laserson
6. The Principal Siaya District Hospital contact for this MOU is Dr. J. Omoto
7. Both parties hereby agree to the terms laid out by this Memorandum of Understanding, and agree that it is in the best interest of the community and all members involved that these collaborative studies are a success.

Signed:

Date \_\_\_\_\_

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Dr. K. Laserson, KEMRI/CDC

Date \_\_\_\_\_

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Dr. J. Omoto, Medical Superintendent, Siaya District Hospital  
Cc: Dr. J. Kioko, Provincial Medical Officer, Dr J. Vulule, Director Center for Global Health Research