

# THE UNIVERSITY of EDINBURGH

This thesis has been submitted in fulfilment of the requirements for a postgraduate degree (e.g. PhD, MPhil, DClinPsychol) at the University of Edinburgh. Please note the following terms and conditions of use:

- This work is protected by copyright and other intellectual property rights, which are retained by the thesis author, unless otherwise stated.
- A copy can be downloaded for personal non-commercial research or study, without prior permission or charge.
- This thesis cannot be reproduced or quoted extensively from without first obtaining permission in writing from the author.
- The content must not be changed in any way or sold commercially in any format or medium without the formal permission of the author.
- When referring to this work, full bibliographic details including the author, title, awarding institution and date of the thesis must be given.

# The Social Lives and Afterlives of a Malaria Vaccine Trial: Partnerships in Practice

Sandalia Genus

PhD Social Anthropology The University of Edinburgh 2017

### Declaration

I declare that, except where otherwise indicated, this thesis is entirely my own work, and that no part of it has been submitted for any other degree or professional qualification.

Sandalia Genus

October 2018

### Abstract

This thesis focuses on the development of a malaria vaccine as an avenue to explore global health partnerships. In the last twenty years, public-private partnerships have become a prominent organizational form in global health. Hundreds of large transnational collaborations and countless smaller collaborations between the public, private and non-profit sectors have been established. Partnerships have been supported by the large increase of donor funding for research and control of infectious diseases in impoverished countries and many aim to develop or provide vaccines, medicines or interventions. Analysts generally agree that partnerships are saving many lives and revolutionizing drug and vaccine development for infectious diseases. However, while partnership is a notion that connotes equity and mutuality, often global health partnerships operate in contexts that involve vast disparities in power and resources and there is little known about the impacts of partnerships on the places where they operate. This raises the questions: How do global health partnerships operate in practice? What are their impacts in the places where they operate?

Addressing these questions, this thesis examines a partnership established to develop the most advanced malaria vaccine, named RTS,S. Based on 17 months of ethnographic research in Tanzania and interviews with representatives of partnering organizations in Belgium and the United States, I trace the development of the RTS,S vaccine from laboratories to its clinical trials across Africa. I explore the social relationships formed between private companies, philanthropic institutions and non-profit organizations in the North, and research institutions and communities in north-eastern Tanzania, where a malaria vaccine clinical trial was conducted. Analyzing the impacts of the malaria vaccine partnership, I focus on community development, construction of infrastructure, the building of human capacity, provision of health care and extraction of data. The focus on partnerships is intended to improve understanding about this ever-increasing social, political and economic formation in global health, and contributes to discussions and debates about how partnerships operate and their role in international development, global health governance and transnational medical research.

### Lay Summary

Global health partnerships comprise of public, private and non-profit organizations and institutions joining together to address global health challenges, such as the creation of new vaccines or drugs. The formation of these partnerships has been on the rise over the last 20 years and analysts generally agree that partnerships have saved numerous lives and improved vaccine and drug development for infectious diseases. However, little is known about how global health partnerships operate and their impacts on the places they operate.

This thesis examines global health partnerships established to develop the most advanced malaria vaccine, named RTS,S. Drawing on ethnographic research conducted in Tanzania and interviews with representatives of partnering organizations in Belgium and the United States, I explore the social relationships formed between private companies, philanthropic institutions and non-profit organizations in the North, and research institutions and communities in north-eastern Tanzania, where a malaria vaccine clinical trial was conducted. Particular focus is placed on community development, the construction of infrastructure, the training of clinical trial staff, provision of health care, and collection of data, both before and after the malaria vaccine clinical trial concluded. This examination of partnerships contributes to an understanding of how partnerships operate and their impact on medical research, international development and global health.

#### Acknowledgements

The production of this thesis has been far from a solitary endeavour and a diverse network of people have supported me during the process of research and writing. Thanks to their various contributions, I was able to carry out this project to completion. For their role in this I would like to express my gratitude.

My deep appreciation goes to the staff who worked at the NIMR Korogwe Research Laboratory. You welcomed me and enriched my research by taking the time to share your thoughts and experiences. I am particularly grateful to the Principal Investigator of the RTS.S vaccine trial in Korogwe for inviting me to conduct my research and supporting my research activities. The appreciation extends to the health care providers and laboratory technicians who worked in government facilities in Korogwe and Handeni Districts. Likewise, I am grateful to those involved in developing the RTS, S malaria vaccine who spoke and met with me. Additionally, thanks to Jessica Kafuko who opened doors to Tanzanian malaria control programs, and to the many researchers, policy makers, donors and implementing partners who gave me generous amounts of their time. I would like to thank Peter E. Mangesho for serving as my Tanzanian supervisor and providing invaluable advice and support. Thanks to the late Tina Mtui at NIMR who guided me through the medical research ethics process and Edward Sixtus Busungu who helped with the process of obtaining a research visa. These people's efforts and support enabled my research.

I am greatly appreciative of the site coordinator at the Korogwe Research Laboratory who opened doors for my research, and the ENRECA research project for providing me a place to live while I was conducting research in Korogwe. I owe special thanks to the people who welcomed me into their homes over the course of fieldwork, including Rebecca Yeong Ae Corey, Merrica Dominick, Nils von der Assen, and Lee Robinson. I am especially grateful to Nicole Cherry whose care and support was unwavering through the many ups and downs of fieldwork.

The University of Edinburgh has offered an inviting and stimulating intellectual home where I received invaluable training and support from many staff and students. I want to express my heartfelt thanks to my supervisors, James Smith and Alex Nading. James Smith has been a tremendous source of support and encouragement throughout the PhD, even when things proved tough. He always

vi

leant an ear - or a book - when needed and for that I am grateful. Alex Nading joined this project a few years in and always showed enthusiasm for my work, provided consistently thorough feedback, and pushed me to dig deeper and think broadly about my research findings.

During the writing process, many people provided invaluable feedback and support. I would like in particular to mention Heid Jerstad, Hannah Lesshafft, Rebeka Thompson, Kathy Dodworth, Hsinyen Lai, Alice Street, Magnus Course, Janet Carsten, Jonathan Spencer and my fellow PhD students in Writing Up class for reading and commenting on chapter drafts or listening to my thoughts as I conceptualized the thesis.

Teaching enriched my PhD and I would like to thank my students in Social Anthropology 1A and 1B, and Health, Illness and Society 3 for helping me grow as a communicator and a scholar.

I would like to express my gratitude to my network of friends and family who provided the social support to bring this project to conclusion: Dorinda MacDonald, Nicole Cherry, Kathy Dodworth, Johanna Katarina Häger Mbise, Hannah Lesshafft, Breck MacGregor, Juliette Oxford, Koreen Reece, Don Duprez, Monica Hauge Skaten, Rebeka Thompson, Hsinyen Lai and Eliza Seaborn. Special thanks to Heid Jerstad who was a steady source of support from the very beginning and was always up for a chat, walk or meal. Thanks and gratitude to my mother and father for far too many things to mention here. During the last stretch to the finish line, my mother provided support and my father helped me think through ideas and proofread my thesis. Your steadfast love and encouragement throughout my life has made this thesis possible.

## **Table of Contents**

| Declarationii   | i |
|---|---|
| Abstractiv  | / |
| Lay Summary   | / |
| Acknowledgementsv   | i |
| List of Figures   | K |
|   | _ |
| Introduction  |   |
| Partnerships in Theory and Practice   |   |
| International Development   |   |
| Global Health15   | 5 |
| Malaria Control and Research22  | 2 |
| Health Care in Tanzania   | 3 |
| Transnational Medical Research  | 9 |
| Methodology, Field Sites and Ethics48   | 3 |
| Chapter Summaries   | 3 |
| Chapter 1: Producing Partnerships: An Account of RTS,S Malaria Vaccine<br>Development and Partnerships61          | 1 |
| Introduction  | 1 |
| The History of Malaria Vaccine Development62  | 2 |
| RTS,S Vaccine Development in Laboratories67   | 7 |
| Testing RTS,S: Phase 1 and 2 RTS,S Vaccine Clinical Trials  | 1 |
| Phase 3 RTS,S Vaccine Clinical Trial78  | 3 |
| Steps Toward Future Provision of RTS,S82  | 2 |
| The RTS,S Vaccine Partnerships84  | 1 |
| Chapter 2: Perceptions of Success: Examining Reflections on the RTS,S<br>Vaccine Partnership and Clinical Trial94 | 1 |
| Introduction  |   |
| The Value of Medical Research   |   |
| Buildings, Infrastructure and Technology  |   |
| The Training and Employment of Staff  |   |

| Health Care, Malaria Control and Health Education | 105 |
|---|-----|
| Community Engagement                              | 109 |
| Success and the RTS,S Clinical Trial              | 118 |

# 

| riai  |     |
|---|-----|
| Introduction  | 121 |
| Theorizing Infrastructure                             | 123 |
| Making a Place for Science                            | 126 |
| A Medical Research Enclave                            | 133 |
| Infrastructure Frozen in Time, Repurposed or Decaying | 136 |
| An Abrupt yet Ambivalent Ending                       | 142 |
| Care and Dependency                                   | 145 |
|   |     |

# Chapter 4: The Boundaries of Care: Material Exchange and Health Care Provision at the End of the RTS.S Clinical Trial .....

| ovision at the End of the RTS,S Chinical Trial                          |
|---|
| Introduction151   |
| Health Care and Medical Research153                                     |
| The Public Health Care System156  |
| Trial-Funded Health Care, Exchange and the Maintenance of Boundaries162 |
| Cutting Ties: The End of the RTS,S Trial173                             |

4 E 4

# Chapter 5: Blood and Paper: Tracing the Collection, Transformation and Movement of Evidence During the RTS,S Clinical Trial.....

| Movement of Evidence During the RTS,S Clinical Trial      | 179 |
|---|-----|
| Introduction  | 179 |
| Producing Credible Evidence                               | 183 |
| Collecting Evidence during Home Visits                    | 186 |
| Paper Forms and Invitation Cards                          | 189 |
| Collecting Biometric and Health Information               | 192 |
| Drawing Blood   | 196 |
| The Movement and Fragmentation of Blood                   | 199 |
| Following the Files: Paperwork, Movement and Digitization | 203 |
| Moving Evidence   | 207 |
| Conclusion  | 210 |
| Bibliography  | 218 |

## List of Figures

| 52  |
|-----|
| 52  |
| 54  |
| 100 |
| 128 |
| 167 |
| 171 |
| 193 |
| 194 |
| 197 |
| 198 |
|     |

### Introduction

What is the most repeated failure in all of global health? It could well be the commitment to eradicate malaria. So why would anyone want to follow a long line of failures by becoming the umpteenth person to declare the goal of eradicating malaria?

There's one reason. We should declare the goal of eradicating malaria because we can eradicate malaria. Today, I want to make the case that we have a real chance to build the partnerships, generate the political will, and develop the scientific breakthroughs we need to end this disease.

My optimism starts with the rush of new actors who are bringing fresh ideas and new energy to the fight against malaria. The biggest players today were not in the game five years ago. The Global Fund for AIDS, TB, and Malaria had just been created. President Bush had not yet announced his major initiative against malaria. Neither had the World Bank. In the past five years, companies like Novartis, GlaxoSmithKline, Exxon Mobil, and Sumitomo have become very involved in the fight. All these groups are now doing more than they've ever done, all at the same time, with a renewed commitment.

The infusion of new money is allowing countries with high rates of malaria to look for the first time at comprehensive, national programs where they can coordinate a wide variety of tools and efforts for maximum effect. No single approach will work alone, but several partially effective approaches can have a huge impact.

- Bill Gates, Malaria Forum: Seattle, October 17, 2007 (Gates 2007)

In October 2007 at the First Gates Malaria Forum in Seattle, Bill Gates urged malaria eradication. While Gates touched upon scientific breakthroughs that would enable eradication, he spoke triumphantly about the building of partnerships between different actors and groups, including the pharmaceutical industry, governments, multilateral institutions, and newly formed global health organizations. At the time, the process of malaria eradication re-emerged as a priority in global health illustrated contemporary practices and thinking that had profoundly changed since the 1990s. Over the previous decade, partnership had ascended as a guiding principle in global health and the number of partnerships established to address critical health issues that affected the poor had grown rapidly (Buse and Walt 2000a; Gerrets 2010).

This upsurge in the creation of partnerships has been encouraged by the World Health Organization (WHO), United Nations (UN), and other global health actors. For example, by the late 1990s, the WHO had suffered decades of underfunding, with its influence and prestige eroding. During this time, a large number of institutions became involved in global health and since the early 1990s, the World Bank had become the largest health donor. In order to revitalize the WHO, Dr. Gro Harlem Brundtland, the Director-General of the WHO from 1998 to 2003, encouraged partnership in health (Richter 2004). Giving a speech at the 51<sup>st</sup> World Health Assembly in May 1998, Brundtland (1998) said,

WHO can and must change. It must become more effective, more accountable, more transparent and more receptive to a changing world... Without a sense of partnership between the Organization and its owners, our work will prove exceedingly difficult. With a unity of purpose we can unleash real momentum for health...

To succeed there are a few basic requirements. First, we need a stronger partnership with the Member States ... Second, we must reach out to others. The global health field has seen a steady increase in the number of actors and stakeholders. This we should not fear. I wish to invite those who have real contributions to make to join us ... We must reach out to the international financial institutions, the World Bank, IMF and the regional development banks ... We must reach out to the NGO community. Their reach often goes beyond that of any official body ... We must reach out to the private sector.

Emphasizing a new mindset for those within the WHO, Brundtland called for partnerships with the private sector, financial institutions, and NGOs in order to "unleash real momentum for health" (Brundtland 1998). Three months after taking office, Brundtland proposed Roll Back Malaria, or RBM, in 1998 as a way to revive the battle against malaria and to help the WHO to transform their institution and improve relationships with outside institutions (Balter 2000). Sponsored in joint with the United Nations Children's Fund (UNICEF), The United Nations Development Program (UNDP) and the World Bank, Roll Back Malaria was formed to bring together UN agencies, bilateral donors, donor governments, industry, research, nongovernmental organizations, and control organizations in the countries affected by malaria. Aimed at reducing the burdens of malaria, Roll Back Malaria was formed to ensure that malaria-affected countries had access to technology, information and financial resources. Since its inception, Roll Back Malaria has raised the profile of malaria, helped countries develop national control programs and persuaded Novartis, a large pharmaceutical company, to provide their malaria drugs at cost. As well, the investments into vaccine development dramatically increased due to this partnership (Packard 2007).

The formation of Roll Back Malaria initiated a surge of partnerships. Key among those was the Global Fund to fight AIDS, Tuberculosis and Malaria, which was formed in 2002. Within a few years, the Global Fund became the leading funding source for infectious disease control and research. Receiving US\$33 billion in funding as of 2015, this partnership is estimated to have helped 9.2 million to gain access to antiretroviral treatment for HIV (human immunodeficiency virus), 15.1 million to obtain tuberculosis treatment, and it has distributed 659 million mosquito nets to avert malaria infection (GFATM 2016). The Global Fund is just one of an estimated hundred global health partnerships that have been established to tackle infectious disease control and research. Globally there are unknown numbers of national- and regional-level partnerships between the private and public sectors (Gerrets 2010). For example, partnerships established between Northern and Southern<sup>1</sup> universities and research organizations have expanded the range and number of partnerships (Crane 2010). Together, these partnerships vary in size, composition and scope, although most tend to have a limited focus on a specific health problem (e.g. vaccination, nutrition, diagnostics) or disease (e.g. malaria, tuberculosis) (Gerrets 2010).

Partnerships have been remarkable in their ability to channel funding to fight disease. Partnerships have stimulated research and development for products and interventions, improved access to health care interventions and put health issues on international and national agendas (Buse and Harmer 2007). As a relatively new way to support the development of new technologies, partnerships have become a dominant and unavoidable modality of engagement in global health (Buse and Walt 2000a; Richter 2004). With unprecedented technological and financial resources, partnerships account for over half of the funding for malaria control and research, with US\$800 million spent in 2007 through partnership-like schemes (Gerrets 2012b; Chataway et al. 2010; Brown 2015). As their institutional form has grown, so

<sup>&</sup>lt;sup>1</sup> Although there are complex histories and politics surrounding the terms, "North" and "South", in this thesis North denotes those countries that donate aid and the South denotes countries that receive aid. It is also broadly geographically correct, as Europe and North America are located to the north of Africa.

has their influence, transforming practices and thinking (Buse and Walt 2000a and 2000b; Gerrets 2015).

An area that has seen considerable partnership activity has been in the development of drugs and vaccines for diseases that predominantly afflict the poor. This sub-type of public-private partnerships is called product development partnerships, or PDP. For-profit companies are largely disinclined to develop technologies to combat diseases of poverty, which are likely to see little financial return. Pharmaceutical companies are forming partnerships with public and private organizations—usually large foundations or governments—to fund products that address the needs of the poor when there is insufficient potential for profit (Biehl 2016; Chataway et al. 2007b). Thus, product development partnerships link products to markets in situations where there is need but a lack of resources or economic incentive (Chataway et al. 2007b; Kale, Hanlin, and Chataway 2013). This shift towards partnerships demonstrates a move away from large pharmaceutical companies carrying out the product development process from beginning to end (Chataway et al. 2007a). Channelling money through these partnerships reduces or removes the financial risks of pharmaceutical companies being involved in the process of product development. These formations have made great strides in developing drugs and vaccines to combat infectious diseases (Widdus 2005; Buse and Walt 2000a; Chataway et al. 2008). Developing medicines, diagnostics and vaccines for Southern contexts necessitates experiments to be conducted in the places where they will be later employed (Street 2014). To support this, product development partnerships established collaborative relationships and partnerships with researchers and institutions in Southern countries (Hanlin 2008; Chataway et al. 2007b).

As a new governance structure, partnerships command great financial resources. Through their interventions and research, these entities impact the lives of millions around the world. Partnerships have become an "established mechanism of global health governance" (Buse and Harmer 2007: 259) and even staunch critics describe partnership as "an unavoidable necessity" (Richter 2004: 45). Analysts generally agree that global health partnerships are saving many lives and revolutionizing vaccine and drug development for infectious diseases (Gerrets 2010).

Despite triumphant statements of achievement, a growing number of scholars (Buse and Walt 2000b; Birn 2014; Crane 2010) have assumed a neo-

Marxist/critical stance towards the rise of partnership in global health and raised concerns about their implications for governance, potential for conflicts of interest, and perpetuation of hierarchical colonial relations. Birn (2014) argues that with partnership, new opportunities have opened for private sector involvement in health, which was once largely the preserve of the public sector. This allows private interests to shape the global health agenda in ways that can benefit industry over people and health systems. Additionally, Buse and Harmer (2007) contend that partnerships alter the distribution of power among organizations, including between the private and public sectors, and between North and South. They caution against the assumption that partnership leads to equality between involved parties, arguing that through the use of the term 'partnership', unequal power relations are disguised.

There is a growing anthropological scholarship about global health partnerships (see, for example, Gerrets 2010, 2012 and 2015; Crane 2010 and 2013; Sullivan 2011; Street 2014; Brown 2015; Nading 2015; Okwaro and Geissler 2015). Some of these anthropologists employ science and technology studies (STS), a theoretical framework that addresses the inherently social aspects of scientific practice. Although this is important to consider when researching science and medicine, this theoretical framework often lacks attention to relations of power and hierarchy, topics of keen interest to many of the anthropologists listed above. Thus, some anthropologists combine STS with neo-Marxist or post-colonial theoretical frameworks to examine the role of wealthy partners in dominating their Southern counterparts and shaping partnerships, institutions and the allocation of resource. However, others contest the idea that power and wealth determine outcomes. Some draw on Foucault, a social theorist who viewed power less as a form of domination coming from above and more as a heterogeneous and diffuse force emerging from all directions. Others employ the anthropologist Mosse (2005) who has written about development projects, which he theorized as operating in a dynamic way to incorporate people's intentions, goals and desires, rather than simply being governed from the top-down.

The anthropologists Street (2014), Brown (2015) and Sullivan (2011) have explored the role of public-private partnerships in health care provision in the global South from within institutions. In a chapter of Street's (2014) book, she analyzes partnerships forged between non-state institutions and a public hospital in Papua New Guinea. She found that hospital administrators valued the ability to establish relationships with non-state actors, which allowed for economic independence from

the government for building infrastructure and procuring equipment. Yet, health care providers felt ambivalent about the limited impacts these investments had on health care delivery, finding that funding from wealthy partners led to the building of enclaved wards rather than improvements for the entire hospital. Sullivan (2011) researched a partnership formed between non-state actors from the North and a Tanzanian hospital to provide HIV/AIDS (acquired immunodeficiency syndrome) treatment. Although this partnership improved infrastructure and equipment, these improvements were enclaved, which set up a division between parts of the hospital that benefitted from donors, and parts that did not. While these two anthropologists focus on the limitations of partnerships and the ability of wealthy donors to dictate the distribution of resources, Brown (2015) discovered something different when exploring partnerships forged between the Kenyan Ministries of Health and USbased global health organizations. Brown uncovered that foreign governments and international agencies were increasingly involved in health care delivery. Although this meant that the power to provide resources had become separated from the state, the legitimacy of the state was actually reinforced because non-state actors were working through state infrastructure to deliver health care.

Anthropologists (Crane 2013; Okwaro and Geissler 2015; Gerrets 2015) have explored partnerships formed to conduct medical research in East Africa. Crane (2013) combines STS and a critical post-colonial perspective to examine power and hierarchical relationships created through a partnership between US universities and Ugandan research institutes to conduct HIV/AIDS research in Uganda. She found that through transnational research relationships between researchers in wealthy countries and researchers in impoverished countries, unequal post-colonial power dynamics were created, whereby Southern researchers had less power to shape the course of research or allocation of resources. Okwaro and Geissler (2015) interviewed African researchers at an East African university and learned that due to insufficient government funding, researchers were required to forge partnerships with Northern research institutions to support research activities. This situation engendered stark difference in power and hierarchy between partners because Northern partners, by virtue of their wealth, had the ability to dominate research activities. However, these author's analysis diverged from Crane's (2013) and they found that despite power asymmetries between partners, African researchers adopted strategies to navigated unequal partnerships and maintain their dignity. Gerrets (2015) draws on Mosse when analyzing a

partnership between Tanzanian- and US-based research organizations to conduct a malaria research and control project. Critiques of medical research partnerships contend that they are a form of scientific colonialism, advancing neoliberal agendas and Northern priorities by virtue of the greater wealth and resources that Northern partners command. But Gerrets found that Tanzanian actors and institutions shaped the partnership by supporting, hindering, exploiting and jeopardizing its aims, and that the partnership facilitated some people in pursuing agendas that strengthened state institutions in Tanzania.

In these accounts, material objects and social relationships played integral roles in the operation of partnership. Although some anthropologists focused on the material inequalities and hierarchies inherent in many North-South partnerships, Brown (2015) and Gerrets (2015) described the ability of resource-poor states to adapt and become integral actors in partnership. Furthermore, instead of focusing on the familiar narrative of hierarchy and domination between unequal partners, Gerrets (2015) and Okwaro and Geissler (2015) shifted the critical narrative put forth by Crane (2013) by uncovering that people in subordinate positions can maintain dignity and enact change through partnership.

Anthropological accounts of medical and scientific research partnerships largely explore how partnerships operate as they are ongoing or examine people's reflections on them after they have ended. Less focus is placed on these kinds of partnerships as they are in the process of ending. Endings are often poignant moments when affect and reflection are heightened. They are a time when people contemplate events that have transpired, try to find meaning, and look to the future. This thesis addresses this gap in the study of partnerships. I bring forth the experiences and reflections people have on partnerships as they end and I examine not only the technical aspects but also the labour, affect and care that people brought to partnership. I focus on three research questions: 1) How do global health partnerships operate and what happens as they end?; (2) What kind of impacts do partnerships have on the places where they operate?; and (3) What are the roles of infrastructure, technology, social relationships, affect, exchange and practices of care in the operation of partnerships?

These questions inspire analysis of the formation and function of partnerships to develop a malaria vaccine named RTS,S<sup>2</sup>. This is the most advanced malaria vaccine to date and has been developed by the British pharmaceutical company GlaxoSmithKline (GSK). RTS,S stimulates human immunity to the most lethal malaria parasite, *Plasmodium falciparum*, and has been formulated for use amongst children. Development of this vaccine has taken over three decades of research and testing. A costly and risky endeavour, RTS,S was made possible through technological and scientific advancements, as well as shifts in funding and institutional structures that promoted product development partnerships and collaborative research relationships. In order to develop RTS, S, partnerships were established among public and private organizations in the United States (US) and Europe, and collaborative relationships were arranged with research institutions across Sub-Saharan Africa to test the RTS,S vaccine in randomized clinical trials from 2009 to 2014 (Cohen et al. 2010; Cohen et al. 2011; Vekemans et al. 2009; Sherman 2009, Chataway et al. 2010). This thesis is based on 17 months of ethnographic research carried out in Tanzania from November 2012 to April 2014. This thesis largely focuses on the last six weeks as the RTS,S vaccine trial and partnerships were ending and two weeks after they concluded, from November 2013 to February 2014. This period of fieldwork was built upon several months of fieldwork carried out amongst malaria researchers and policy makers in Dar es Salaam. As well, from January 2014 to June 2015, in-person and video call interviews were conducted with malaria vaccine scientists at a pharmaceutical company in Belgium, a malaria researcher in the United Kingdom, and clinical trial coordinators/funders in the US.

In order to situate the subsequent analysis, I review relevant literature about partnerships in theory and practice and bring to the fore debates about the impacts of partnership on governance, transnational relationships, and medical research. After the literature review, I describe my methodology and the research sites, followed by a summary of the thesis chapters.

<sup>&</sup>lt;sup>2</sup> "RTS,S is a scientific name ... [that] represents [the vaccine's] composition. The 'R' stands for the central repeat region of *Plasmodium (P.) falciparum* 'circumsporozoite protein (CSP); the 'T' for the T cell epitopes of the CSP; and the 'S' for hepatitis B surface antigen (HBsAg). These are combined in a single fusion protein ('RTS') and co-expressed in yeast cells with free HBsAg. The 'RTS' fusion protein and free 'S' protein spontaneously assemble in 'RTS,S' particles." (MVI-GSK 2015: 1)

#### **Partnerships in Theory and Practice**

The development of the RTS,S malaria vaccine and its testing in Tanzania has led to the establishment of partnerships and collaborative relationships between public, private and civil society organizations. Partnership was established as part of nation-state governance, took hold in international development, and became popular in global health and medical research. In order to draw theoretical insights to the study of partnership, I review key literature on intersecting realms of inquiry: international development, global health, malaria control and research, health care, and transnational medical research.

#### International Development

Escobar (1995) argues that we are unable to think of the world outside of the lens of development and underdevelopment. For over 60 years, the concept of development has been a framework to understand the relationship between the affluent North and less affluent South (Mosse 2005; Crane 2013). Development discourses and practices are built upon the premise that certain places are not only economically deprived but also temporally behind or stuck in the past (Hornborg 2008; Fabian 1983). Africa and places in Asia and Latin America are often conceptualized as underdeveloped places of poverty, backwardness and need. In order to overcome underdevelopment, development practices aim to modernize and bring low-income settings forward in time and up to the same level of progress and growth as is found in Europe and North America. This is typically done through improved infrastructure, health outcomes, education, and access to science and technology (Escobar 1995).

Global health has arisen as a sub-field of international development. Since the colonial era, policy makers have perceived a connection between health and development and tried to improve health outcomes in order to improve economic development. Thus, health has been considered a prerequisite for economic development, and vice versa (Packard 2016). Despite being portrayed as something new, global health has its roots in international development and operates in a similar manner: wealthy Northern donors intervene and provide tools to change circumstances in resource-poor settings so as to bring about improvements in development. Due to this intertwining of the fields, it is important to

understand international development and the rise of partnerships to better understand global health partnerships. Furthermore, literature about partnerships in international development explore shifts in governance and power, which will shed light on ways to understand partnership in global health.

First, some background: Partnerships and collaborations, such as the ones established to develop and test the RTS,S malaria vaccine, are relatively recent entities in global health and only came to prominence in the late 1990s. However, over the past 50 years, partnerships have been a burgeoning governance formation around the world, taking on multiple forms. Partnerships between the public, private and non-governmental sectors is a practice that began in government administration in the 1970s and expanded to other sectors over time (Bovaird 2004; Brinkerhoff 2002). As a liberalizing mechanism, partnerships arose as a way to scale back the role of governments and public organizations in the production and delivery of public services and products. With the rise of neoliberal ideology, government and public organizations began to be perceived as overly bureaucratic, clumsy and plagued by fiscal problems. Markets were viewed as able to allocate resources effectively and reduce costs, while non-profit organizations were seen as values driven, more efficient, and able to take the place of government in service delivery. Additionally, societal issues began to be thought of as increasingly complex with governments unable to tackle them in isolation. Partnerships that combined the public, non-profit and private sectors were thought to allow each sector to bring its strengths to bear on a particular issue. Governments that partnered with the private and non-profit sector allowed for the scaling back and creation of a lean government more focused on support of the voluntary and private sectors with minimum interference and regulation. This process was thought to bring efficiency and cost-effective provision of products and services to the public (Bovaird 2004; Broadbent and Laughlin 2003; Brinkerhoff and Brinkerhoff 2002).

Neoliberal ideology impacted nation-state governance, bringing forth greater numbers of partnership. By the 1980s and 1990s, similar forces were at work in international development. Before partnership, alternative forms of governance operated between Northern nation-states and Africa. During colonialism, colonial governments governed colonies in a hierarchical fashion. Propagating a child and adult metaphor, colonizing countries presented themselves as guardians of colonized people and lands, protecting the colonized from their own irrationality and foolishness (Abrahamsen 2004; Crewe and Harrison 1998). At independence,

African states took over governing from colonizing governments. However, from the 1960s onwards, resource-rich countries and institutions of the North, including the Bretton Woods institutions—the World Bank, United Nations, International Monetary Fund—maintained a central role in the governance and provision of aid to African countries (Fowler 2000).

This level of involvement through development aid led to accusations and fear of neo-colonialism, imperialism and a continuation of hierarchy and inequality between North and South (Abrahamsen 2004; Crewe and Harrison 1998). Critics of development argue that donors treated local organizations as passive recipients that were unable to conduct their own affairs because they were unevolved, acting with childlike incompetence in corrupt and undemocratic ways. Although the mechanisms of governance have changed, development aid in the 1980s and 1990s evoked fears of neo-colonialism due to the conditions donors placed on the aid provided to Southern states. An example of conditions placed on aid were structural adjustment programs (Crewe and Harrison 1998). Many African nations experienced structural adjustment programs, which were instituted by the International Monetary Fund, World Bank and other national and international organization. Structural adjustment included a package of reforms that reduced state spending and increased revenue through privatization, international trade liberalization, market deregulation and state devolution. African governments had to adhere to these conditions in order to receive a lower interest rate for existing loans or access new loans (Rottenburg 2009). As Crewe and Harrison (1998) contend, these conditions placed on aid were symptoms of donors who assumed that they understood what a country needed more than its own government. With over a hundred countries subjected to these programs, criticism grew that governments lacked local ownership of the development process (Fowler 2000).

Several scholars (Fowler 2000; Abrahamsen 2004; Crewe and Harrison 1998) assert that the shift towards partnerships was a reaction to the preceding policy era that focused on top-down, hierarchical relationships between North and South. Abrahamsen (2004) argues that donors employ the concept of partnership as a response to long-standing and persistent charges of intervention. Partnership signals an attempt to demonstrate a return of influence and power to African states. Recipients of aid are no longer commonly called "counterparts" or "beneficiaries", terms that are perceived as passive. Rather, those receiving aid are portrayed on equal terms, as partners, and the process of aid provision is conceived of as a

cooperation between equals. With paternalistic approaches being unpopular, those receiving aid are expected to assume greater responsibility for development, improving institutional or organizational capacity to sustain programs after donors have stopped providing aid (Crewe and Harrison 1998).

At the same time, emphasis shifted from governments acting as principle actors and engines of development. Non-governmental organizations and market forces had been at the fringes of development until the 1980s, marginally contributing but not fully accepted into the official aid system (Fowler 2000). But with the rise of neoliberal ideology and the rolling back of the state through structural adjustment programs, non-governmental and private organizations became more involved in development, filling gaps left by a less-funded public sector. Through this process, partnerships began to include a larger range of actors (Rottenburg 2009; Fowler 2000).

Fowler (2000) asserts that partnerships came to the fore in international development in the 1970s, providing a guide for the quality of relationship that should be attained between non-governmental organizations and their Southern beneficiaries. Partnership became a key word indicating a political, moral, ideological, humanitarian solidarity between Northern and Southern organization. However, Crewe and Harrison (1998) contend that partnership in development describes a vast range of relationships between actors and that the word 'partner' encompasses a spectrum, without differentiation about the types of partner, their context, or history.

As I will be exploring the organizational structure and relationships between Northern and Southern actors and entities throughout this thesis, it is important to expand on the debates about hierarchy and domination in partnership. Several scholars question if partnerships return power to resource-poor countries. For some, partnerships are a positive shift in international development. As Maxwell and Riddell (1998), two international development analysts, argue, partnership can offer the chance to establish an aid relationship that is founded on equality and mutual respect. Partnership can also increase Southern actors' capacities for leadership and ability to design and implement development strategies. However, these analysts acknowledge that there are intrinsic difficulties in achieving equality in relationships and contend that there are different degrees of partnership, anywhere from strong to weak. Donors prefer weak forms of partnership as they fear losing their influence over how development resources are used. This makes

"genuine partnerships" difficult to achieve, leading to "potential pit-falls" to the transferring of power to aid recipients (258). But from the perspective of these analysts, partnership is still a worthwhile goal to strive for.

Some scholars draw on the neo-Marxist idea of "dependency theory", which critiques development as a way to sustain the economic order of class inequality and keep impoverished nations poor (Lewis and Mosse 2006; Escobar 1995). From this critical viewpoint, partnership is a form of rhetoric, disguising old policies and practices that perpetuate the domination of the North over the South (Abrahamsen 2004). Much like the terms, "participation", "community" and "empowerment", which are buzzwords in development, partnership evokes a sense of warm mutuality. But this term is vague, making it attractive because it legitimates donors, allowing them to claim equality between actors while the specifics of the arrangements are left unclear to outsiders (Crewe and Harrison 1998; Cornwall 2007). Fowler (2000) claims that the use of the term partnership makes arrangements between North and South seem inclusive, harmonious and benign, subtly precluding other interpretations. This legitimizes the intrusiveness of foreign concerns into the domestic concerns of resource-poor countries. Thus, for these critics, partnership in development is a veiled continuation of unequal colonial relationships.

The anthropologists Crewe and Harrison (1998) take a similarly critical stance towards partnerships in international development. They assert that in practice, there can be difficulties creating mutuality and equality between partners when there are vast differences in resources and power. Crewe and Harrison (1998) found through their respective experiences in development projects in Sri Lanka and Kenya that despite partnership being the ideal, in practice equal partnership was difficult to attain. Although colonialism had ended, donors still tend to be Europeans who assist or provide aid to former colonies. This arrangement allows donors more power and control over recipients who are unable to repay donors for their assistance and aid. Often, development projects reflect the preferences of the donor instead of the partner or recipients. Structures of power created by people's identities (skin colour, age, gender, nationality and class) and their institutional position in the partnership also shaped interactions between people, making it difficult for people to interact as equals. Thus, Crewe and Harrison (1998) argue that the very nature of exchange between Northern donors and Southern recipients is inherently unequal and, at times, coercive. Donors rarely acknowledge this inequality. Although the move towards 'partnership' is a laudable

ideal, they emerge in a context rife with structural inequalities. Thus, in practice, partnership does not redress inequality.

A third position employs Foucauldian critiques, whereby the development "order" is sustained by a power-knowledge regime that is enabled through discursive and non-discursive means that has effects beyond the intentions of the state, bureaucracies, institutional actors or individuals (Lewis and Mosse 2006). Abrahamsen (2004) and Ferguson (1994) draw on Foucault to argue that rather than a form domination, partnership is a productive form of power. Governmentality, to apply Foucault's term, is operating in partnership, whereby people's subjectivities are shaped in such a way that they come to govern themselves. In this formulation, power does not come from above but is diffuse and heterogeneous, stemming from all directions. This is a useful way to understand governance when territorial, state and bureaucratic frameworks have expanded and shifted in a global era, with decision-making and power centres decentralizing and pluralizing towards nongovernmental and semi-autonomous institutions and organization. In this situation, rather than donors setting the agenda and coercing Southern states into behaving in particular ways, people monitor and govern themselves.

Abrahamsen (2004) argues that partnerships produce modern and selfdisciplined people and states. This process leads to their enlistment as responsible actors who develop themselves. This is because over time, people internalize neoliberal ideals that not only structure behaviour but constitute people's values, norms and identities. Governmentality works by the inscription of developing countries as agents, active creators of their own development and future. This configuration confers not only freedoms, opening new possibilities for action and decisions, but also duties and obligations. In order for states to receive aid, they must demonstrate a level of self-governance and learn to practice freedom in a responsible manner. Once aid has been received, auditing technologies are employed as instruments of power and governance in order to bring about new forms of conduct.

Some anthropologists draw on Foucault's theory of power to write about international development. Lewis and Mosse (2005) contest the idea that development has an inner logic that leaves little room for disjuncture and contingent practices. These authors contend that rather than there being a bureaucratic rationality, the inner workings of development present complex practices and discourses of diverse actors that work in different institutions and organizations. Li

(1999) conducted long-term research in Indonesia and argues that claims to order are contested, fragile and built on compromise, which means that hegemony cannot be imposed but must be worked out. This complex way of understanding development can be applied to partnership. Instead of viewing partnerships as a mechanism for imposing order or domination, partnership can be understood as a productive force. Mosse (2005) furthers this argument, drawing on his experience of a UK Department for International Development (DfID) funded development project in India. He found that even in situations of inequality and power imbalances, marginalized people can manipulate project discourse, refuse participation, and make claims for investment, employment and social protection. Rather than partnership being achieved through imposition and domination, they can work through promises of inclusion and incorporation.

This section of the introduction has described the rise of partnership as a form of governance and organizational formation in the international development sector and provided an overview of the various scholarly debates about partnership and hierarchy between donors and receivers. A majority of the literature offers various theorizations of partnership and how they operate, largely drawing on the critical/neo-Marxist or Foucauldian traditions. However, anthropologists provide ethnographic insights into how partnerships in international development function. Crewe and Harrison (1998) uncovered that although partnership—with its attendant meanings of equality and mutuality—is an ideal, historically-rooted economic, political and social differences place Southern partners at a distinct disadvantage in respect to Northern institutions and actors. This situation makes genuine partnership difficult to attain. And yet, Li (1999) and Mosse (2005) describe with their ethnographic research that partnerships—even hierarchical ones—can be contested and productive. These various interpretations of partnership provide valuable insights to analyzing how partnerships operate in global health. I turn now to an examination of the literature about global health partnerships.

#### **Global Health**

Global health is a field concerned with improving the health of people in countries once called Third World, or underdeveloped, and now often termed as low-income countries. The roots of global health began with 19<sup>th</sup> century endeavours to contain infectious diseases and offer development assistance. At the

time, large-scale campaigns to prevent infectious diseases were largely conducted in the colonies of the global South by colonial authorities (Packard 2016). When colonialism ended, health campaigns were dominated by the public sector through the WHO. Although philanthropic organizations—such as the Rockefeller Foundation—played a role in health interventions, there was little direct involvement of the private or non-profit sectors. Partnership did exist but they usually were limited to relationships between the public sector, donor agencies and the governments of recipient countries. Often relations between different sectors were adversarial and competitive (Birn 2014; Buse and Walt 2000a).

This situation shifted 20 years ago when the global health field experienced "revolutionary" changes (McGoey et al. 2011: 2). Due to a broad range of factors, an increasingly diverse group of actors came to populate the global health landscape, changing it dramatically. What led to this exponential growth in global health partnerships? First, there was increased public awareness of re-emerging and new infectious diseases that accompanied the spread of HIV/AIDS and increased prevalence of malaria and tuberculosis. Second, political attention to global health rose in the late 1990s with the G8 and UN General Assembly meetings focusing on infectious diseases, their potential to destabilize political and economic systems, and impact on national security (Huckel Schneider 2008; McGoey et al. 2011). Third, the prevailing ideology of the 1980s and 1990s favoured privatization and market forces. Donors perceived the UN system as inflexible, wasteful and overly bureaucratic and the WHO had its core budget frozen. This led to an increase in public funds being channelled through non-governmental organizations, a phenomenon that also occurred in the international development field. These factors led to a growth in financial aid available for health, initiated a discourse about new forms of collaboration between the private, civil society and public sectors, and led to the formation of numerous partnerships (Walt and Buse 2000a; Packard 2016; Gerrets 2010 and 2015).

The proliferation of partnerships is entwined with the dramatic increase of funding for global health. In 1990, US\$2.2 billion of financial aid went towards health globally (Michaud 2003: 1) and by 2007, this reached US\$21.8 billion (Ravishankar et al. 2009). While in the 1990s a majority of newly formed partnerships were unable to attract funding from traditional donors, such as UN agencies, bilateral donors and the World Bank, there was a substantial increase in funding for them a decade later (Gerrets 2010). This was due in large part to the

emergence of new philanthropic donors, especially the Bill and Melinda Gates Foundation. Since launching in 2000, the Gates Foundation has provided funding for global health that has dwarfed contributions by most national governments (McGoey et al. 2011). The Gates Foundation have made several high-profile and substantial contributions to partnerships, with US\$750 million to The Global Alliance for Vaccines and Immunization (GAVI)<sup>3</sup> in 1999 and large contributions to launch the multi-billion-dollar Global Fund in 2002. Becoming the largest global health funding mechanisms for infectious diseases, these partnerships in turn spend a large share of their funding through partnerships. Through this substantial funding for partnership, a clear signal was sent that this was the way forward (Gerrets 2010).

Once the Global Fund had been launched in 2002, new organizations entered the global health field, including the US President's Malaria Initiative (PMI) and PEPFAR—the US President's Emergency Plan for AIDS Relief (Gerrets 2010). As well, the Gates Foundation marshalled other donors to support their global health initiatives. This includes bi-lateral donors, which contribute ten times what the Gates Foundation gives each year (Birn 2014). These organizations increased funding for communicable diseases research and control in resource-poor countries to previously unseen levels, with funding often channelled through partnerships. With this increase in donor funding for global health, an enormous shift occurred and relations between institutional actors rearranged. Traditional health donors, like bilateral agencies and UN organizations such as the WHO, no longer dominated as they had up until the 1980s (Gerrets 2010). Partnership allowed businesses to demonstrate increased social responsibility, and for the public sector, there was an infusion of much needed funding and resources for neglected health issues (Walt and Buse 2000a and 2000b).

This shift in global health has led to several impacts on the way global health actors and entities operate. Birn (2014) critically examines these developments and contends that although business and philanthropic interests have been involved in international health for some time, in contemporary global health they have become central figures and their role has been formalized through partnerships. Business interests play a key role in global health with pharmaceutical companies being

<sup>&</sup>lt;sup>3</sup>GAVI was formed in 1999 with a grant from the Bill and Melinda Gates Foundation and brings together the World Bank, WHO, UNICEF, the pharmaceutical industry, donor governments and representatives of developing countries. Having received US\$7.2 billion from donors between

granted an unprecedentedly large role in policymaking by joining partnerships. Through its financial support and partnerships, the Gates Foundation has also assumed a dominant role in global health by funding and collaborating with the WHO, the World Bank, multi-lateral agencies and a range of partnerships. This allows the Foundation to shape the global health agenda. With the influence of business and philanthropy, global health policies draw on business principles that focus on profit-making as the propeller of product development, policies and other activities. Overall, Birn (2014) argues that partnerships allow corporate agendas to be imposed. Public sector organizations like the WHO have had their authority and functionality undermined through underfunding and vilification. Consequently, global health programs focus on narrow, top-down and single disease programs.

McGoey et al. (2011) are also critical of recent global health practices, asserting that despite the steep hike in funding for health, global health inequities have thus far not diminished. In fact, the world is more inequitable than it was 50 years ago. This has led experts and activists to question the funding priorities of global health organizations and point out that when one disease or approach is prioritized over others, others are neglected. Birn (2014) points out that the Gates Foundation, with its large endowment and ability to influence global health policy, has focused global health initiatives on the innovation and delivery of technological fixes and targeted interventions, despite the plethora of demographic and public health research that demonstrates that improved working and living conditions account for gains in life expectancy. For example, the Foundation's most prominent efforts have been the support of vaccine development. In 2010, the Gates Foundation pledged US\$10 billion over 10 years to vaccine development and delivery and sizeable grants were given to the Malaria Vaccine Initiative and GAVI (Birn 2014). Over time there has been a reduction of health care to the simple delivery of drugs on both international and national levels (Petryna 2009). Biehl (2007) has called this the "pharmaceuticalization" of health. Often, donors have insisted on funding only technological and disease-specific vertical programs. This focus on vaccines and drugs means there is less money given to improving health care systems (Biehl 2016). Therefore, although analysts generally acknowledge that there have been many lives saved through partnerships (Gerrets 2010), these

<sup>2011</sup> and 2015, this partnership influences market mechanism to develop and procure vaccines (Storeng 2014; Muraskin 2004; GAVI 2017).

scholars argue that global health partnerships have a narrow scope and respond to the symptoms of inequity—illness and disease—and neglect to address the root causes of ill health, which is global inequities in wealth.

Partnerships and leading global health institutions, with their narrow and technological focus, divert attention from the need for health care infrastructure, access to comprehensive medical care, better housing, environmental protections, and the strengthening of health systems in resource-poor countries (Kelly and Beisel 2011; Biehl 2016; Petryna 2009). However, this focus on technological solutions to ill health is, as Birn (2014) contends, a way for private partners to commercialize their products and channel public money into the private sector. McGoey (2012) argues that this is the entire goal of philanthropic and business involvement in health, that it is a strategy to accrue profit. The involvement of philanthropies and businesses also enhances reputations, provides tax subsidies and expands markets, which all generate capital (Birn 2014).

With large sums of funding going towards technological solutions, this accounts for the great amount of activity around product development partnerships (Buse and Walt 2000a). Private, for-profit organizations tend to be uninterested in developing technologies for diseases of poverty, which are anticipated to see little financial return. To overcome public and market 'failures' to develop drugs and vaccines for neglected diseases, partnerships have been formed between industry, public, philanthropic, and non-profit organizations (Chataway, et al. 2007b; Kale et al. 2013; Buse and Walt 2000a and 2000b; Widdus 2005). Funding for these partnerships largely stem from public or philanthropic sources and allow industry to share the costs, risks and benefits of scientific research into new drugs and vaccines (Buse and Walt 2000a; Widdus 2005). These partnerships are born out of the idea that private and public sectors cannot resolve historically rooted inequalities in isolation (Chataway and Smith 2006; Gerrets 2015). Product development partnerships, like the one to develop the RTS,S malaria vaccine, blur traditional distinctions between private and public sector's responsibilities and aims (Buse and Walt 2000b).

The first product development partnership was the International AIDS Vaccine Initiative (IAVI), which was launched in 1996 (Wheeler and Berkley 2001). By the mid-1990s, there was an unprecedented growth of partnerships to tackle diseases found in low-income countries. Commanding vast sums of public and private funding, partnerships were formed between public, non-governmental

organizations (NGOs) and private, for-profit organizations (Widdus 2005; Walt and Buse 2000a; Gerrets 2010). For the private sector, partnerships have allowed corporations to demonstrate increased social responsibility, and for the public sector, partnerships have brought an infusion of much needed funding and resources for neglected health issues (Walt and Buse 2000a).

Although there has been a great amount of partnership activity around vaccine and drug development in the last 20 years, the development of drugs and vaccines occurred differently in the past (Walt and Buse 2000a; Chataway et al. 2010). After the Second World War, there was a clear division of labour between health research and drug development. Public research institutions, usually universities, carried out basic research and major pharmaceutical companies typically conducted applied research and developed and manufactured the drugs they produced. In the 1970s, attempts were made to form partnerships between private and public entities involved in health research and development. Taking some time to be established, the new public-private partnerships began consolidating relationships between universities and pharmaceutical companies. By the 1980s, both public and private sectors were anxious about reduced revenue flows and productivity as collaboration was increasingly encouraged by policy makers. In 1980, the Bayh-Dole Act was passed in the US as a piece of legislation that aided technological transfers between universities and industry, allowing for rapid commercialization of research. In the 1990s, institutional environments changed with biotech firms growing and coming to serve as upstream suppliers to pharmaceutical companies, and pharmaceutical companies subcontracting work at various stages of research and development to other organizations. However, large pharmaceutical companies maintained dominance in the pharmaceutical sector because clinical trials remained so costly, which limited the ability of small firms and public institutions to develop drugs and vaccines (Sunder Rajan 2006; Chataway et al. 2010).

During the 1980s and 1990s, there was a growing recognition that actors in health research and product development could not meet broad health goals in isolation. Expenditures for research and development have concentrated in Northern countries with only 10% of money for health research being spent in the South, even though 90% of the global burden of disease resides in the South. This 10/90 health research gap raised concerns about the withdrawal of the pharmaceutical industry from developing and manufacturing medicines, diagnostics

and vaccines for the diseases of poverty (Buse and Walt 2000b, Jentsch and Pilley 2003, Kale et al. 2013). To improve this, product development partnerships began to be formed, largely initiated by the public sector.

While gaining popularity as a governance formation and funding mechanism, product development partnerships have opened new paths for innovation and widened the space for participation in health research and development (Buse and Walt 2000a). These partnerships have benefited from increased investment from public sector and philanthropic donors that prefer to see their money given to a partnership rather than to public or for-profit organizations and companies. Backed by major institutions and foundations, partnerships have grown in credibility, filling a vacuum that established private and public organizations alone were unable or unwilling to fill (Chataway et al. 2010, Gerrets 2015).

Since product development partnerships are a relatively new way to organize, fund and govern the development of products for neglected diseases, little social science research has been conducted on how they operate. Many scholars address product development partnerships in a theoretical way, drawing on literature to describe their organizational structures and their impacts on governance (Widdus 2005; Buse and Walt 2000a and 2000b; Chataway et al. 2007a; Chataway et al. 2010). Chataway et al. (2010) have described product development partnerships in a positive light. These scholars state that partnerships bring together different actors around objectives, facilitating cooperation and sharing information collectively, and that the organizations involved in partnerships have the capacity to devise creative solutions that surpass the limited perspectives of the individual partners. But little evidence has been collected about whether partnerships actually live up to these assertions (Gerrets 2010). Furthermore, Buse and Harmer (2004) find that a majority of literature on global health partnerships lack a focus on power relations and yet relations of power are at the centre of partnerships. These two public health researchers raise the concern that partnerships allow powerful actors undue influence in global health to promote their own interests. For example, partnerships open new opportunities for private companies to influence and exercise power in domains once controlled by the public sector, such as setting priorities in health and diseases control. From the perspective of these two scholars, the discourse of 'partnership' is a rhetorical device that portrays partnership as inevitable and a 'win-win' for those involved and thus effectively denies inequalities exists between actors and institutions. This

discursive construction means that power differences are left unarticulated, making it difficult to criticize partnerships and contest the influence of powerful actors.

Some qualitative research has been conducted about product development partnerships. Chataway and Smith (2006) examine IAVI when it was a burgeoning organization. Through a literature review and interviews with IAVI partners, staff and funders, the authors find that IAVI serves as a case study of how partnerships have shaped capacity building and awareness of HIV/AIDS in the places it operates. Hanlin (2008) conducted qualitative research on IAVI in Kenya, exploring collaborative activity and the role of innovation in health care, knowledge exchange and capacity building. The anthropologist, Nading (2015), conducted ethnographic research on the partnerships formed to develop a dengue vaccine at the US Centres for Disease Control in Puerto Rico, uncovering the intersection of biosecurity, capital and humanitarian interest in shaping the aims and activities of global health actors. Few of these scholars, save for Nading (2015), critically examine product development partnerships by focusing on power relations, hierarchy, dominance and inequality between actors, organizations and places. As well, none of these accounts describe the end of partnerships, people's reflections on partnership as they draw to a close, or the affect, labour and exchange that is involved in partnership. My thesis fills these gaps in the literature through analysis of the RTS,S vaccine partnerships and clinical trial.

Once product development partnerships have been formed to develop a drug or vaccine to combat infectious diseases found in resource-poor countries, often partnerships and collaborative relationships are formed between Northern and Southern institutions to test products. I now shift to a description of malaria and an overview of the history of malaria control and research.

#### Malaria Control and Research

Until this point, I have explored the rise of partnerships in international development and global health. However, partnerships have also arisen in the field of malaria control and research. In this section, I draw on historical, scientific and social science literature to provide background on malaria, malaria research and control, and the rise of partnerships aimed at addressing malaria.

Malaria is a parasite that has been infecting humans for over 500,000 years, shaping our evolution and our societies (Shah 2010). *Mal'aria*, meaning 'bad air',

was a term used by medieval Italians who believed the disease was caused by poisonous vapours emanating from swamps. During the medieval period, the incidence of malaria often mapped onto impoverished areas and was associated with people who were unfortunate to sleep without a roof over their head, work in marshes, or those who fought in the trenches. Thus, the disease was associated with class and place (Packard 2007; Kelly and Beisel 2011).

Through scientific research, it began to be understood that malaria was caused by something other than marsh vapours. Through many decades of scientific research, human malaria is now understood to be caused by a protozoan parasite transmitted by female mosquitoes<sup>4</sup>. To date, six species of this single-celled parasite are known to infect humans, although three<sup>5</sup> are largely zoonotic diseases found amongst non-human primates. Of the six species, *Plasmodium falciparum* and *P. vivax* most commonly infect humans. While all malaria species can cause debilitating illnesses, *P. falciparum* is accountable for the vast majority of deaths (Ashley et al. 2018). Currently, half the world's population is at risk of contracting malaria, which is transmitted through the bite of a mosquito. However, a vast majority of malaria cases occur in sub-Saharan Africa where *P. falciparum* is endemic in many countries. In estimates from 2016, there were 216 million cases of malaria and 445,000 deaths. Those most vulnerable to malaria are children under the age of five, who make up two thirds of malaria deaths (Crawley et al. 2010; WHO 2018).

The life cycle of malaria requires two hosts—a human and a female *Anopheles* mosquito—and begins with a human being bitten by an infected mosquito. While a mosquito feeds on a human, sporozoites (the infective form of the malaria parasite) enter the human blood stream. The parasites travel to the liver and invade it, dividing into as many as thirty thousand daughter cells over several weeks, months or years, depending on the malaria species. These daughter cells are then released into the blood stream, invading the red blood cells. Inside the red blood cells, the parasites grow and multiply and eventually cause the red blood cells to burst with new parasites, which then spread and invade other red blood cells. The continuous destruction of the red blood cells leads to anaemia, as well as the periodic fever and chills that characterize malaria. After several days, male and

<sup>&</sup>lt;sup>4</sup> Of the 450 known species of *Anopheles* mosquitoes, only 70 transmit malaria (Shah 2010).

female gametes form and when the human host is bitten by a mosquito again, these sexual forms are ingested by the mosquito where they produce new sporozoites. After seven to fourteen days, the mosquito is ready to infect a human with malaria once again (Vekemans et al. 2009; Casares, Brumeanu and Richie 2010).

Malaria affects the blood, kidneys and brain, leading people to suffer from anaemia, fever, headache and vomiting. *P. falciparum* can develop into cerebral malaria, which blocks the capillaries and small blood vessels in the brain, stopping oxygen from properly circulating. This can lead to neurological or learning deficits, or even death. This strain of malaria particularly affects pregnant women, who have a lower immunity to malaria, and those who are not immune, such as children. People living in malaria endemic regions tend to develop tolerance to malaria if they are continuously exposed to it for many years and by the time people reach their early teens they often attain functional, clinical immunity. This means that although they still experience the symptoms of malaria, they do not tend to suffer from severe malaria and have a lower chance of dying from the disease. However, that resistance diminishes if people spend time in other areas where no malaria or a different species of malaria is transmitted (Doolan et al. 2009; Sherman 2009; Ashley et al. 2018).

Malaria is more likely to be found between 45° north and 40° south and is endemic in many regions of Africa. However, it has not always been confined to tropical regions and was once found in some regions of Europe and North America, including Britain. It is thought that malaria came to Europe from either Africa or Asia Minor. Malaria spread across Europe over the centuries, reaching England by the 14<sup>th</sup> century and the Americas through European explorers, African slaves, colonists, and conquistadors (Packard 2007; Sherman 2009).

Although one of the oldest diseases in existence, population growth and changes to the environment have put malaria mosquitoes in closer contact with humans and increased its transmission. Agricultural pursuits, especially rice production, have altered the natural tropical ecosystem in some regions, creating open areas of water that are ideal for mosquito breeding sites. Destruction of forests, development of irrigation systems, cash crop cultivation and man-made lakes also result in increased mosquito populations and malaria prevalence in

<sup>&</sup>lt;sup>5</sup> These include the species *Plasmodium knowlesi*, *P. cynomolgi* and *P. simium* (Ashley et al. 2018).

endemic regions. Instead of attaining progressive development, as was the aim with many of these ecological changes, these activities have often resulted in higher rates of malaria (Packard 2007; Packard and Brown 1997; Desowitz 1991). This is one illustration of the way that malaria is social, "connected with the economic and political life of the people who inhabit the regions where it dominates" (Celli 1900, cited in Packard 2007: 111).

During colonialism, Africa was dubbed "the white man's grave" due to the high rate of death from malaria. Since malaria made colonization difficult, Europeans had an interest in understanding and controlling the disease. It was understood that people native to Africa were comparatively less affected by malaria but the nature of this immunity was unknown (Doolan et al. 2009; Sherman 2009). Despite little understanding of malaria, drug therapy was developed with the discovery of cinchona trees in Peru in the 16th century. The bark of these trees was used to successfully treat malaria and by 1820 the active agent was isolated to make quinine. Development of this drug made it possible for Europeans to live in Africa (Rocco 2003; Sherman 2009).

In order for prevention and treatment of malaria to expand beyond the use of quinine, people had to gain a better understanding of how malaria was transmitted. The *Plasmodium* parasite was first observed by Charles Laveran, a French army physician posted in Algeria in the late 1870s. Laveran examined blood from a feverish artilleryman, using a microscope to spot the parasite. In the 1890s, Ronald Ross, an English surgeon who worked in India as part of the Indian Medical Forces, discovered the association between mosquitoes and the malaria parasite, uncovering the life cycle of *Plasmodium* in the mosquito. In 1898, Giovanni Battista Grassi, an Italian scientist, was able to identify that it is the *Anopheles* mosquito that transmits malaria<sup>6,7</sup> (Packard 2007; Shah 2010; Sherman 2009).

<sup>&</sup>lt;sup>6</sup> These discoveries were first documented by Western physicians but might not have been uncovered had it not been for conflict, the expanding French and British Empires and the assistance of non-Western people (Packard 2007; Kelly and Beisel 2011). <sup>7</sup> Europeans were not the only people to think there was a connection between mosquitoes and malaria. Robert Koch, a German scientist, was sent by the German government to the Usambara Mountains in Tanganyika, then part of German East Africa. He stayed there between 1897 and 1898 and found that the locals called malaria "*Mbu*" because they thought it was carried by the *mbu*, which is the Swahili word for mosquito. But with the use of European technologies such as the microscope and with employment of the scientific method, this connection became well understood and documented by Europeans (Sherman 2009).

With malaria better understood, various control measures were developed in the twentieth century, spanning from the technical-biomedical to the socio-medical. These various approaches related not only to a spirit of optimism upon discovery of the connection between parasites and mosquitoes but also the institutional arrangements that involved a multitude of international, national, private and public actors. However, it was unclear how best to combat malaria around the world. Following from Celli, an Italian physician and parasitologist, some believed that high disease prevalence related to general squalor and was best tackled with development measures, including economic reforms, agricultural innovation, and improvements in housing. Others, influenced by British and American scientists, thought that the fight had to target the vector, an approach termed 'species sanitation'. This approach involved systematic identification and destruction of the breeding grounds of the *Anopheles* mosquito through draining marshes, oiling ponds, and filling ditches with concrete (Packard and Brown 1997; Packard 2007; Kelly and Beisel 2011; Eckl 2017).

Most prominent twentieth century malariologists acknowledged the economic and social forces that shaped malaria epidemiology and the need for economic and social development. Yet malaria control efforts seldom incorporated these broader views and control efforts increasingly relied on narrow solutions. By the 1950s, malaria control largely took the form of long lasting pesticides and antimalarial drugs. Mass distribution of pharmaceutical drugs (chloroquine at the time) was cheaper because it did not require much pre-existing infrastructure or specialist knowledge. And dichlorodiphenyl trichloroethylene (DDT), a pesticide created by a Swiss company in the 1930s, was found to kill insects at low concentrations. World War II created the capacity and impetus to produce large quantities of this pesticide and it was found that irrespective of dire sanitary conditions or a lack of shelter, blanket application of DDT could quickly control insect-related disease (Packard 2007; Kelly and Beisel 2011).

This shift in control methods was accompanied by a change in institutional arrangements. During the post-war period, an international system of governance was developed through the Bretton Woods Institutions. Growing out of the International Monetary Fund (IMF), the WHO was established, which was a separation that institutionalized public health. This institutional separation led people to consider malaria as a public health problem and not a problem of economic or social development. This narrowed the scope of possible interventions

to those focused on the health of individuals and populations and not on the boosting of local economies or improving ecological management. Also, colonial governments were being dismantled, public health was internationalized, and medical expertise became centralized with public health decisions largely made in New York and Geneva by large multinational organizations, which shifted control from local governments. Additionally, there was great faith in technology and science to develop underdeveloped countries. Under these circumstances, policy makers set the goal of eradicating malaria through the deployment of technology with the aim of developing poorer nations and expanding markets (Packard and Brown 1997; Packard 1997 and 2007)

At this time, DDT was the tool of choice and by 1950 many countries depended on routine spraying for their antimalarial programs. So promising were the results that the global program to eradicate malaria from the world was launched in 1955 with technical aid provided by the WHO and funding from UNICEF, USAID and local governments. This program led to the distribution of drugs for those infected and the widespread spraying of DDT in many regions of the world, which led to striking short-term beneficial outcomes. Costing nearly US\$1.4 billion over 14 years, this funding peaked by 1965 and by 1970 eradication was achieved in 18 countries, mainly in places with stable economies and well-developed infrastructure, and/or island nations (Packard 2007; Kelly and Beisel 2011).

In other places, widespread spraying was more costly and difficult. The mosquito species *Anopheles* eventually adapted and rates of malaria surged in many places. As well, the excessive use of DDT in the Tennessee Valley and elsewhere helped launch the modern environmental movement and calls were made for this spraying to end. Donors one by one withdrew funding and in 1969 the WHO abandoned its strategy of eradication, seeing no end to the demands on funding. It was recommended that control programs be carried out by individual states and integrated into primary health care systems (Packard 2007; Desowitz 2002; Sherman 2009; Carter 2014).

Africa was never truly figured into widespread malaria control programs at the time. Policy makers thought that extensive DDT spraying would lead to longterm problems as it would interrupt naturally acquired immunity to the disease. In this conceptualization, malaria in Europe and the Americas was not the same as malaria in Africa (Packard 2007)

By the 1970s, malaria eradication was no longer on the agenda and malaria control and research funding was greatly reduced. Countries that had been dependent on international funding for vertical programs found their health care infrastructures weakened and they were unable to adequately deploy malaria prevention methods. Anti-malaria programs shifted toward treatment, involving the delivery of drugs to those in need, with preventive methods being abandoned. However, resistance to chloroquine grew and the incidence of malaria resurged as the malaria parasite developed resistance. This situation lasted for decades (Packard 2007; Kelly and Beisel 2011). New drugs for malaria and mosquito prevention tools have been created over time<sup>8</sup> but the story is the same: it works miracles at the beginning but eventually resistance grows along with the number of malaria cases. *Plasmodium* has a great ability to develop resistance to drugs, while the Anopheles mosquito has a rapid and ongoing speciation process. Thus, both parasite and mosquito develop resistance to drugs and sprays in a quick pace. complicating malaria prevention and control. Each method, unless 100% effective, forces the mosquito or the malaria parasite to adapt and evolve. In this way, malaria control and prevention shape the biology of the parasite, vector, and the disease epidemiology (Mackinnon and Marsh 2010; Desowitz 2002; Packard 2007; Vekemans, Leach and Cohen 2009; Dondorp et al. 2009).

For decades after the failed attempt to eradicate malaria, funding for malaria research and control fell drastically. But as described at the beginning of this introduction, since the 1990s there has been a paradigm shift amongst global health actors. Armed with new tools and unprecedented funding, the Gates Foundation has reignited efforts to not only tackle malaria but to eliminate it. Unlike the previous elimination program, sub-Saharan Africa is the primary focus of these renewed efforts. Also, where elimination efforts during the 1950s and 1960s were spearheaded by international governance structures like the WHO and underpinned by social welfare systems, contemporary efforts are directed by public-private partnerships, large-scale development donors and international research collaborations. The Gates Foundation, WHO, PMI and other organizations have entered into public-private partnerships and ushered in an era of philanthrocapitalism, applying business techniques to philanthropy, whereby actors

<sup>&</sup>lt;sup>8</sup> For more information on the various ways that people have fought, controlled or eliminated malaria, see Mitchell 2002, Carter 2012, Packard 2007, Desowitz 1991 and 2002.

aim to make a profit while doing good socially (McGoey 2015; Kamat 2013; Kelly and Beisel 2011; Packard 2007). As discussed above, the first of such partnerships for malaria was RBM, which as of 2015 had over 500 partners from the private sector, multilateral organizations, malaria-endemic countries, and academic and research institutions. As partnerships for malaria research and control have proliferated, RBM has played an important role in coordinating these partnership, as well as mobilizing resources and action, and developing a global strategy (Chandler and Beisel 2017; Gerrets 2015b).

Although this period began with an emphasis on the social dimensions of malaria, it eventually turned towards more narrowly focused methods. Organizations involved in malaria control have increasingly tackled the disease with a particular vision of public health, one linked to neoliberalism and growth and supported by capital, science, technology and expertise. Framing malaria control and research for two decades, emphasis has been placed on research that seeks technological solutions, such as vaccines or new drugs, and programs that deploy technological solutions. It is thought that through infusions of funds, advances in genomics and application of technological tools, malaria can be out-paced (Eckl 2017; Litsios 2015; Kamat 2013; Packard 2007; Kelly and Beisel 2011; Chandler and Beisel 2017).

Current malaria control programs to address *P. falciparum* and the *Anopheles* mosquito include the provision of artemisinin-based combination therapies (ACTs), insecticide-treated nets, intermittent preventive treatment (IPTp) for pregnant women, indoor residual spraying (IRS) of buildings, larvicide treatment of standing water in cities, improved malaria diagnosis, including the use of rapid diagnostic tests (mRDTs), and behavioural change and communication (PMI 2013; THMIS 2012; Mandike 2013). With resistance growing to ACTs and insecticides, malaria research is aimed at devising new drugs, insecticides and vaccines, and monitoring malaria rates, the rise of mosquito and parasite resistance, and the impacts of malaria programs (Dondorp et al. 2009; Ranson et al. 2011; Greenwood and Targett 2011). Funding for research and control programs derive from institutions, governments, foundations, companies and organizations working in partnership with in-country malaria control programs and research institutions (Gerrets 2010).

Several social scientists (Packard 2007; Birn 2014; Kelly and Beisel 2011; Kamat 2013) criticize contemporary malaria control programs. They argue that

although malaria is back on the health agenda and health outcomes have improved due to public-private partnerships, these efforts have taken a narrow focus. Disease research and the creation of technological solutions have been chosen over broader development and public health initiatives. As Kelly and Beisel (2011: 84) state:

The current shift in commitment from management to technological fixes represents an abandonment of local capacity. The innovative solutions ... are a matter of transfer: technologies invented *somewhere* are retooled and relocated to improve life *elsewhere* (emphasis in text).

But as Packard and Brown (1997: 187) point out, this narrow focus ignores the economic and social determinants of malaria, allowing global health actors "not to be concerned with thorny problems of poverty and inequalities in the distribution of land and capital resources". Kamat (2013) contends that the factors that underpin persistent malaria, including historically and structurally entrenched inequalities, widespread poverty and climate change, are enormous challenges but they need to be addressed in order to truly eliminate malaria.

In the last two decades there has been a growing interest in malaria amongst anthropologists. In 1997, a special issue was published in Medical Anthropology, edited by Packard and Brown. Since then, two other special issues have been published: In 2015, 'Re-imagining malaria - A Platform for Reflections to Widen Horizons in Malaria Control' in *Malaria Journal*, edited by Dr. Julian Eckl and Dr. Susanna Hausmann-Muela; and in 2017, 'The Anthropology of Malaria: Locating the Social' in *Medical Anthropology*, edited by Clare I.R. Chandler and Uli Beisel. These special issues have included articles that explore malaria control through time and in a range of places around the world. These special issues join anthropology books, journal articles and PhD theses that examine malaria from many angles. Some publications have explored how people understand and address malaria (Marsland 2005 and 2007; Iskander 2015; O'Neill et al. 2015; Langwick 2008; Kamat 2006, 2009 and 2013). Others examine various malaria control methods, including drugs (Kamat 2013; Kamat and Nyato 2010; Gerrets 2010), IRS (Montgomery et al. 2010), ITNs (Marsland 2005; Shum 2010), mRDTs (Chandler et al. 2012; Beisel et al. 2015; Umlauf 2017), larviciding (Kelly and Lezaun 2014; Kelly and Beisel 2011; Kelly 2015), repellents (Kelly et al. 2017) and the development of malaria vaccines (Geissler et al. 2008; Turnbull 1989). A few anthropologists have described the institutional arrangements that underpin malaria control and research (Litsios 2015; Eckl 2017), while others have charted the rise of data collection and audit in tracking

malaria and control measures (Gerrets 2012a; Tichnor 2017). Also, quite a few of these publications have focused on malaria in Tanzania (i.e. Marsland 2005; Kamat 2006, 2009 and 2013; Kamat and Nyato 2010; Kelly 2011; Kelly and Beisel 2011; Kelly and Lezaun 2014; Langwick 2008; Gerrets 2010, 2012b and 2015).

Of particular salience to my thesis is Gerrets' PhD thesis (2010), which is currently the only in-depth ethnography written about a public-private partnership aimed at carrying out malaria research and control. In his thesis, Gerrets explains that many actors, including the Gates Foundation and WHO, have encouraged and funded the formation of partnerships. These actors often claim that partnerships are the best way to fund and carry out malaria research and control. However, some critique partnerships, questioning their ability to attain equality between Northern and Southern actors when these relationships are marked by dependencies and large financial differences. However, little research has been conducted about the social dynamics and inner workings of partnerships in context and over time to support either argument. To fill this gap in the literature, Gerrets explores the research activities and internal organization of a global health partnership (given the pseudonym of CONTACT) formed to research the ability of ACTs to delay or reverse malaria drug resistance in south eastern Tanzania. Throughout the thesis, he uses the term 'partnership' to describe both a type of organization (a public-private partnership) and a type of relationship based on equality, respect, mutuality and consensus (157).

In one ethnographic chapter, Gerrets (2010) complicates assumptions often made of global health partnerships, finding differences between the theory and practice of partnership while exploring labour relations between the different levels of staff at CONTACT. Staff held aspirations for egalitarianism and viewed labour relations as ideally upholding social justice and morality. Additionally, Tanzanian cultural particularities tend to favour communitarian beliefs and values. However, Gerrets finds that the ideals of partnership are difficult to sustain when they come up against stratification, which is a necessary feature of most complex organizations, and neoliberal economics. Although Southern actors higher up the strata were able to use their influence and power to shape decision-making, further down the hierarchy inequalities were particularly pronounced. This creates tension between the ideal of partnership and the realities. What resulted was instances when staff, particularly those at a lower stratum (especially data collectors) felt unequal and even abused by those at a higher stratum. This impacted how much staff worked

and if they recorded data correctly, with rumours circulating about data collectors fabricating data when they felt disrespected. These experiences of staff at different strata complicates simplistic conceptualizations of partnership, demonstrating that under local and global political-economic pressures, partnership can be a way to gain power for some while leading to oppression and exploitation of others.

In the next chapter, Gerrets (2010) explores the inter-organizational dynamics and structures of the CONTACT partnership. First, he attempts to map the various infrastructures, actors, funds and objects that constitute the partnership over time and space, although their multitude and complexity makes this difficult. Gerrets highlights not only the highly visible actors involved in the partnership but the less visible, ordinary ones, such as electricity, roads, and so on. Second, he describes the fluidity of the partnership. Gerrets finds that the agency of actors was enabled or constrained at different times and that a level of flexibility was necessary in the operation of the partnership. This flexibility allowed staff to handle the various challenges that arose, such as periods when funds or drugs were difficult to obtain. During times of difficulty, actors within and outside of Tanzania came together to enable the research to proceed. This chapter effectively demonstrates that partnerships are complex processual and relational networks.

In the final ethnographic chapter, Gerrets (2010) further describes the social dynamics and inner workings of the CONTACT partnership. He explains that publicprivate partnerships face increasing demands from donors and recipients for measurable results of success. In response, partnerships multiply techniques and mechanisms of monitoring and auditing as a way to govern from a distance. However, this has implications for the production of knowledge. Despite the contextual and fluid meaning of malaria, through data collection, the CONTACT partnership "shapes the production of authoritative scientific facts" (341), which impacts how malaria is seen and understood. Data collectors act as linguistic and conceptual brokers who shape the contours of data by "mediating between local discursive realities and global biomedical science represented through surveys and interviews" (403). This means that the composition of the data is highly impacted by the context of data collection, including how data collectors engage with and ask questions of informants. The wider political-economic and socio-cultural aspects are rarely addressed during data collection and the ambiguities and miscommunications between data collectors and informants went unrecorded. The data that was recorded was moved, digitized and thus reified, making its veracity impossible to

verify. In this way, data collectors—and the CONTACT partnership more widely play a role in shaping scientific knowledge about malaria and how the disease is acted upon.

Overall, Gerrets' (2010) PhD thesis has many parallels to my own. It offers an in-depth examination of a particular partnership and demonstrates its wider impacts on knowledge production and malaria control. His thesis, along with other anthropological research about malaria, serve as important work that my thesis builds upon as a I explore a specific research partnership that produces new knowledge that may impact future malaria control programs. However, none of these anthropological accounts describe a malaria research partnership as it is ending, which is a gap in the literature that my thesis fills. Turning from a discussion about partnerships in malaria research and control to focus on the local level, below I provide historical background about health care provision in Tanzania and the rise of partnerships as a mode of providing resources in low-income settings.

## Health Care in Tanzania

To understand the role of global health partnerships in health care provision, I weave together secondary literature and ethnographic studies of health care in Tanzania.

The Tanzanian health care system was created during German colonial rule of East Africa, which spanned 1884 to 1918 (Iliffe 1998; Turshen 1984). Malaria, the leading public health issue in Tanzania, has impacted much of the country throughout its history, save for high-altitude regions that are malaria free (Iliffe 1979). Under German colonial rule, attempts were made to reduce death and sickness caused by malaria, several years after it became understood that the disease was transmitted by the anopheline mosquito. This discovery, made by Ronald Ross in 1896, led to efforts to protect groups considered relevant to the economy, including urban residents, some African labourers, and Europeans (Clyde 1967; Beck 1977; Sherman 2009). After the First World War, the British assumed control of the colony, renaming it Tanganyika. From 1919 to 1961, health services grew under British rule with the rural health system expanding (Turshen 1984; Iliffe 1998). Over that time, a growing proportion of the population was exposed to measures to control malaria (Clyde 1967; Beck 1977). During the colonial era, health care provision for Africans was patchy and fit an enclave pattern, whereby most health care investment was found in places that were directly productive to the economy. The health system was unsuited to the geographical realities and population distribution, as well as the financial difficulties of a poor country. Most doctors in Tanganyika were European and a majority of health services were provided to military personnel, or in urban centres and near plantations to keep the mostly male labour force healthy and able to work. These medical services were qualitatively better than those available in other places that were not economically productive or of interest to colonial governments, including places that served as labour reserves (Giblin 2005; Iliffe 1998; Turshen 1984; Vaughan 1991; Feierman 1985). Mission hospitals provided health care and became the only places that would treat African women and children (Feierman 1985; Vaughan 1991).

This situation changed after independence from British rule in 1961 (Heggenhougen and Lugalla 2005). From the 1950s to the late 1970s, decolonization and national independence movements across Africa were in full force and there were aspirations for ameliorating policies centred on the ability of the state to bring about self-determined development. Administrative structures established during colonialism were dismantled, replaced with modern state administrative apparatuses. National infrastructure projects were undertaken, including the establishment of factories, roads and power stations (Rottenburg 2009).

In Tanzania, Julius Nyerere, a graduate of the University of Edinburgh, was a teacher who rose to power and pushed for independence from British rule. He is fondly called *mwalimu*, or teacher, or *Baba wa Taifa* (Father of the Nation) by people throughout Tanzania and to this day, his picture hangs in many rooms throughout the country. In 1960, Nyerere became Chief Minister under British Trusteeship and in 1961, he became president when the colony of Tanganyika became independent from British rule. Joining with the island of Zanzibar in 1964, the country acquired the name of Tanzania. From 1961 to 1967, socialist policies began being instituted but this period did not significantly differ from the colonial period. Although racial discrimination was put to an end, the private sector—particularly religious organizations—remained the dominant health care provider and the focus was on curative rather than preventative health care provision (Heggenhougen and Lugalla 2005). However, the number of health care providers increased and from 1961 to

1970, the number of Tanzanians who became doctors increased in number from 12 to 123 on the mainland of Tanzania (Iliffe 1998).

In 1967, the government of Tanzania was headed by the Tanganyika African National Union (TANU), the only official political party at the time. TANU redefined its development direction and political ideology and with the publishing of the Arusha Declaration, became professedly socialist. Rejecting the capitalist route to development, TANU vowed to create a socialist society through the principles of "ujamaa" (family hood) and self-reliance (Nyerere 1968; Heggenhougen and Lugalla 2005). Nyerere's vision for Tanzania was based upon enlarging government control over social and economic life (Gerrets 2015). Banks, schools, insurance firms, and health institutions and other companies and institutions were nationalized (Heggenhougen and Lugalla 2005). The Arusha Declaration contained little about health but the adoption of socialism opened the country to the influence of medical systems found in other socialist countries, such as China (Iliffe 1998). Health care was made universally accessible for all citizens and there was an effort to improve access to health services and distribute them equitably in an attempt to eliminate poverty and disease (Heggenhougen and Lugalla 2005). The government viewed health care as both an ends and a means of developing Tanzania. Health care could improve development by improving health outcomes and making healthier communities, and simultaneously, improvement in health care provision demonstrated how far Tanzania had come in its development (Harrington 1999).

From 1973 to 1976, the Tanzanian government engaged in the *ujamaa* village campaign, whereby some 6 million people were relocated into nucleated settlements. This was largely undertaken as a welfare and development project by a relatively weak and benign state. The aim was to facilitate communal farming, make communities easier to control, and provide social services, such as clinics, schools and clean water. Some communities resisted relocation and in some instances the government used force to move people into planned villages. This campaign had a disastrous effect on agricultural production and the state was forced to import large quantities of food between 1973 and 1975. In the end, the planned villages failed as human communities, units of production, and as a way to deliver social services. The government subsequently abandoned this form of social engineering (Scott 1998; Jennings 2002).

The Tanzanian government found other ways to improve access to health care and drugs. During the 1970s, Nyerere banned commercial involvement in

health care (Gerrets 2015). Large investments were made into constructing a few big hospitals, as well as health care centres and dispensaries in rural settings. A study conducted in 6 of the country's 20 regions indicated that by 1979, 92% of the population lived within 10 kilometres of a health facility and 70% within 5 kilometres. Rural Medical Aids, Medical Assistants and Community Health Workers (inspired by China's 'barefoot doctors') were trained, and emphasis was placed on preventative over curative health care provision. Health care provision was largely dominated by public institutions, such as the Ministry of Health (Heggenhougen et al. 1987; Heggenhougen and Lugalla 2005).

Until the mid-1980s, Tanzania experienced economic growth, providing free health care and building social infrastructure (Shiner 2003; Evans and Ngalwea 2003). The Tanzanian government expanded health services, building more rural health facilities than many other resource-poor countries. By 1985, one-third of villages had a health facility. By the 1990s, Tanzania had four large national referral hospitals, a regional hospital in every region, 152 district hospitals for the 106 districts, and 3,000 dispensaries. This extensive system of rural health care was the envy of many African countries. As well, by 1991, about 700 doctors were produced, along with hundreds of nurses and medical officers (Iliffe 1998). However, the equitable distribution of health services in rural parts of the country were not fully realized due to economic and personnel shortages (Heggenhougen et al. 1987; Heggenhougen and Lugalla 2005; Gerrets 2015).

By the 1980s, much of the fervor of decolonization in Africa ended with many of the ambitious goals left unachieved (Rottenburg 2009). At that time, an economic crisis hit Tanzania due to a rise in oil prices in the late 1970s coupled with a fall in export values (Shiner 2003). The elements of failure that led to this crisis were built into post-colonial settlements that rooted the economies in old trading and commodity dependence that continued to benefit Europe and industrial countries (Bush 2007). By the 1980s, Tanzania had a deficit that led to heavy borrowing in the form of loans from the International Monetary Fund and the World Bank. These organizations instituted structural adjustment programs, a set of strict stipulations that governments had to follow in order to access new loans or receive a lower interest rate for existing loans (Heggenhougen and Lugalla 2005; Rottenburg 2009). These structural adjustment programs were a new form of governance and adhered to the prevailing neoliberal ideology of the times. Structural adjustment led to the reduction of state spending and increased revenue through privatization,

international trade liberalization, market deregulation and state devolution (Rottenburg 2009).

Structural adjustment was primarily imposed to cater to the interests of loaning banks and countries and to secure the international financial system (Packard 2016). However, it had a devastating effect on the health care system in Tanzania. Public health care and other welfare systems eroded and this either directly affected health through the cutting of financing for the health care system, or indirectly affected health through changing the economy and the scaling back of welfare programs. The government privatized state run services, the role of the private health care sector increased, and health care services became decentralized (Heggenhougen and Lugalla 2005; Buse and Walt 2000b; Rottenburg 2009).

In 1993, the Tanzanian state began to recover health care costs by charging user fees for access to services, making access to these health facilities more difficult for those who were impoverished (Shiner 2003; Bush 2007; Ake 1996). Current neoliberal models of health care provision emphasize the need to cut costs and shift costs onto users with user fees, termed "cost sharing" (Green 2000: 404; Dilger 2009; Ellison 2014). The health of the Tanzanian population declined, reflected in rising mortality and morbidity rates and increased barriers to accessing medical care in rural areas (Shiner 2003).

Tanzanian health care is currently provided by a mixture of government, private for-profit and private not-for-profit (e.g. mission hospitals) services. The government delivers care in more than half of the facilities throughout the country and health coverage is better than in many other Sub-Saharan African countries. As well, children under the age of five and pregnant women are exempt from user fees. Yet, the quality of services can be poor, infrastructure decaying or non-existent, and there can be inconsistent supplies of drugs in government health facilities (Shiner 2003; Sullivan 2011). In 2014, US\$137 per capita was spent on health care in Tanzania<sup>9</sup> (WHO 2015a). Even with greater investment from government and international donors, years of underfunding and a general lack of funding for rural areas has profoundly impacted Tanzania's public health care and people's engagement with it (Green 2000).

<sup>&</sup>lt;sup>9</sup> For comparison, health care expenditure for the United Kingdom was US\$3,377 per capita (WHO 2015b).

Estimates suggest there are only 0.39 nurses and 0.25 clinical staff (doctors, clinic officers and assistant medical officers) for every 1000 people (Manzi et al. 2012). Although this number is low, there are a variety of health care providers in Tanzania. There are medical doctors with five-year degrees; clinic officers with three-year degrees; assistant medical officers with two-year diplomas; and assistant clinic officers with two-year certificates. These health care providers are often trained at the medical schools in Tanzania (Heggenhougen and Lugalla 2005). There are also three kinds of nurses: assistant nurse, certified nurse and registered nurse, with each receiving increasing amounts of training. Community health workers also play a role in improving access to health care. Although not a panacea for an underfunded health care system, community health workers can be on hand in communities to provide emergency care and advice on sanitation, nutrition and hygiene and link patients to primary health care providers (Heggenhougen et al. 1987; Mubi et al. 2016; Haines et al. 2007; World Vision 2015).

Rottenburg (2009) argues that although structural adjustment programs were instituted with the aim of improving ailing economies and securing debt repayment, they had the effect of hollowing out already dysfunctional states and diminishing the core meaning of citizenship. This hollowing out and loss of institutions that could negotiate the claims and interests of different actors has meant that conflicts have flared up across Africa, and there have been various kinds of state failure, including corruption, abuse and violations of law, and constant humanitarian disasters. With state structures often ailing, the policies of international development organizations shifted from the support of state functions to the direct support of populations to bring about their own development. The bypassing of governments shifted from being an illicit act and became a sign of a genuine concern for impoverished populations.

Attracted by catastrophes and emergencies, there has been an increase and expanding range of heterogeneous actors and networks of public and private organizations involved in the operation of states and their health care and medical research activities. With crises being viewed as humanitarian emergencies, public and private organizations intervene by deploying biomedicine. State privatization and devolution led to a process of projectification, whereby corporate civil society agencies such as non-governmental organizations (NGOs) assumed the functions of project agencies from government institutions by receiving aid and became accountable for achieving project goals. Often this shift in responsibility was a

conditionality set by donor agencies (Rottenburg 2009). However, over time, it has become difficult to distinguish emergencies from chronic poverty. Rottenburg (2009) argues that by articulating the impacts of chronic poverty as a humanitarian emergency, Western public and private organizations legitimate their interventions in Africa, undermining the sovereignty of Africa states. Thus, systemic creation of zones of exclusion and humanitarian emergencies—a product of structural adjustment programs—may be an intended outcome that legitimates Western intervention in Africa.

The shift towards projectification and increase in non-state actor involvement has impacted the Tanzanian health care system. Gerrets (2015) contends that despite decades of structural reforms that hollowed out government institutions in Tanzania, they remain stable, strong and prominent since the Nyerere era. However, as Sullivan (2011) found in Tanzania, the health care system is highly reliant on donors and NGOs for funding. Often, transnational NGOs provide targeted interventions for particular diseases, like malaria and HIV/AIDS, within government health facilities. In this way, NGOs not only provide health services in parallel to the state, services are often provided from within the state. This makes it difficult to discern what is public and private health services. Sullivan (2011) describes these situations as biomedical enclaves within the Tanzanian public health system, which seek to mobilize and improve biomedical practices and technologies to expand the provision of health care to the poor.

Since the implementation of health sector reforms in 1999 to 2000, the Tanzanian Ministry of Health has aimed to increase salaries, improve working conditions and update training for workers through the implementation of health sector reforms. Although some progress has been made towards these goals, other initiatives, including the reforming of management systems and equipment and drug supply, has been prioritized by outside donors who provide funding for these activities. Through these initiatives, NGOs and other donors have sponsored programs to make available resources that the state has promised but been unable to deliver (Sullivan 2011).

## Transnational Medical Research

Much like Tanzanian health care provision, funding for medical research in Tanzania was routed through public institutes up until the 1980s. Currently, the

National Institute for Medical Research (NIMR) operates all medical research institutes in the country but this institution has its roots in colonial medical research. The colonial East Africa Bureau of Research in Medicine was established by the British to conduct and coordinate medicine and science in Tanganyika, Kenya and Uganda. In 1961, at the tail end of the British colonial era, the East African Medical Research Council (EAMRC) was established in place of the colonial institution. However, funding ran out for the EAMRC in 1977 in the wake of the collapse of the East African community. NIMR was founded in 1979 by the Tanzanian Parliament as a para-statal organization under the Tanzanian Ministry of Health and took the place of the EAMRC. But during the 1980s and 1990s, public sector institutions like NIMR had their funding cut, leading to an inability to support research activities (Gerrets 2015).

At the same time, Northern researchers required places to test new vaccines, drugs and medical devices for infectious diseases in the places where they would potentially be deployed (Street 2014). Several anthropologists (Angell 1997; Cooper 2008; Sunder Rajan 2007; Sariola and Simpson 2011; Petryna 2005 and 2009) have examined transnational medical research conducted in resource-poor settings, an activity that has sharply increased over the past few decades. This increase has largely been precipitated by regulations put in place in the early 1990s that limited medical research conducted on prisoners in the US. To make up for the loss of human volunteers, the US Food and Drug Administration (FDA) actively encouraged clinical trials to be conducted outside of the US in order that the safety and efficacy of new drugs be ascertained.

With Southern research institutions lacking funding and Northern researchers requiring human bodies for medical research, Northern researchers saw an opportunity and established partnerships with Southern research institutes and researchers. In the last two decades, partnership has become a dominant mode for supporting research activities in resource-poor settings. It supplants earlier concepts, such as colonial surveys and expeditions of imperial science or post-colonial provisions of expertise and funding in the name of developmental solidarity. Using the phraseology of partnership and collaboration—which typically denotes relationships between equals—this indicates a wish to distance current global health practices and structures from previous traditions of tropical medicine and international health that were paternalistic and top-down in relation to poor nations. Indeed, global health partnerships are often lauded as involving collaboration and an equal balance of control and responsibilities for activities (Crane 2010; Okwaro and Geissler 2015). Partnership can also bring about material benefits for Southern institutions. As the anthropologist Gerrets (2010 and 2015) discovered in Tanzania, when NIMR established partnerships with foreign organizations in the North, this led to multiple benefits, including improvements in human capacity building, infrastructure and health care provisions. However, partnerships and collaborative relationships formed between Northern and Southern institutions often involve stark differences in funding and resources between partnering organizations and actors (Crane 2013; Okwaro and Geissler 2015).

The dominant form of transnational scientific production in sub-Saharan Africa (outside of South Africa) operates not as corporate drug trials, as is found in Eastern Europe and Asia (e.g. Petryna 2009; Sunder Rajan 2007), but as publicly funded collaborative research centres or field stations. These research centres are often run by a para-statal organization affiliated with a Northern scientific organization. Although the main source of funding stems from national government institutions, a growing number of public-private partnerships have been funding medical research in Africa. These public-private partnerships, receiving private funding from sources such as the pharmaceutical industry, shape and contribute to public medical research. Operating in many ways like corporate research, much research conducted in Africa involves a predominantly local staff conducting research on short-term work contracts. Northern institutions control the scientific production process, with data often moved to and analyzed in Northern institutions (Geissler 2012). This description mirrors how the RTS,S vaccine partnership and clinical trial functioned in Korogwe, Tanzania.

Scholars have interpreted these shifts in the operation and funding of African medical research in various ways. Partnership in health research is "imbued with positive moral value" and is a term that is accompanied by ideas of equality, freedom, mutuality, shared responsibility, balance of power, and reciprocal obligations (Okwaro and Geissler 2015: 3). As well, the discourses about transnational research are largely about how partnerships are beneficial for both wealthy donors and impoverished African centres and employees. Binka (2005) argues that North-South partnerships have a positive impact on medical research. He describes how North-South relationships were once predicated on steep hierarchies, with Northern institutions acting as donors and Southern institutions as a receiver of aid. This arrangement was often described as scientific colonialism,

with the North dictating the agenda and providing the funding, which left Southern researchers at the mercy of partners in the North. However, Binka contends that since the 21<sup>st</sup> century, partnerships are closer to "true partnerships" (2005: 207). This shift towards more equal, "true partnerships", largely stems from Northern institutions attempting to redress inequalities, include researchers from the South in decisions and policy planning, and improve capacity and professional networks.

Although Binka (2005) views contemporary partnerships as an improvement over past relationships, others scholars remain skeptical of medical research partnerships. Relationships between the actors involved in global health are diverse and challenging and partnerships are performed in contexts of profound inequalities in resources and power that stem from colonial and post-colonial relations. In practice, partnership and collaboration between actors and organizations may not be emancipatory or equal, leading to conflict (Crane 2010; Okwaro and Geissler 2015). Jentsch and Pilley (2003), having worked at a UK university and conducted qualitative research in Thailand and Bangladesh, question how equal partnerships can be when there are historically shaped structural inequalities that privileges Northern actors and allows them to dominate over Southern actors.

The anthropologist Crane (2010) examined research partnerships between US academic institutions and African research institutions. She contends that the term 'partnership' describes a wide range of ideal relationships and activities, including public health interventions and building of capacity to administer research funding. These different interpretations of the term indicate that partnership is a loose term, one that is hard to pin down. Due to this lack of attention to the activities and meanings of partnership, the complex power dynamics and diverse arrangements at play are obscured and collaborative relationships between North and South can resemble a donor/aid recipient relationship. Partnership may bring material benefits, such as buildings, scientific infrastructure and employment opportunities. However, these benefits may come with expectations that Northern funders can impose their will on African partners. Due to this arrangement, Crane (2010) contests the idea that contemporary global health relationships have shifted from colonial power relations.

Okwaro and Geissler (2015) argue that there is little examination of African scientists and their experiences. As discussed above, they filled this gap by conducting ethnographic research amongst African scientists in East Africa and found partnership brought employment, research infrastructure, and built technical

capacity. However, African scientists were dependent on Northern collaborators because government support for research was limited. This situation led to conflict and a sense of ambivalence amongst many African scientists towards collaborative research relationships. Building on this research, my thesis explores the experiences and reflections of African researchers and staff who were involved in the RTS,S vaccine partnerships and clinical trial in Tanzania, and I describe the views and experiences of their Northern partners.

While I have discussed the rise of partnerships between Northern and Southern research organizations, transnational medical research necessitates the formation of social relationships between researchers and the people and communities involved in medical research. These relationships are shaped by ethical research codes and guidelines. Ethical codes articulate how people and organizations should relate to one another, including the care that needs to be provided to research participants. Ethical codes arose in response to the Tuskegee experiment, which involved African Americans purposely denied treatment for syphilis, and Nazi atrocities during scientific experiments in Germany. In the last three decades, medical research ethics has been a growing area of debate, coinciding with the rise of research conducted in resource-poor contexts. Ethical regulations, such as the Nuremburg Code, the Belmont Report and the Declaration of Helsinki, have been increasingly refined to regulate medical research conducted in impoverished settings (Molyneux and Geissler 2008). Additionally, the FDA has played an active role in shaping ethical protocols by establishing a set of standards in commercial pharmaceutical drug testing with the guideline, Good Clinical Practice (GCP), set by the International Conference on Harmonization (ICH). In multi-sited research, these standards allow resulting data to be comparable across research sites. Many countries signed on to the ICH-GCP, eager to attract investments in the production of pharmaceuticals. National agencies were set up to monitor and standardize the conduct of clinical trials and countries created ethical review boards that monitored and regulated the conduct of globalized research to ensure the protection and rights of participants (Sunder Rajan 2007; Simpson and Sariola 2012; Petryna 2005 and 2009).

Anthropologists have criticized transnational medical research and the ethical codes devised to control medical research practices. Some anthropologists (Crane 2013; Street 2014; Petryna 2009) contend that medical research organizations have been attracted to conduct research in impoverished settings due

to the ill health that arises from poverty and gaps in health care provision, which creates sick and treatment naïve populations willing to be tested with new interventions. In this way, research organizations working in impoverished places have been opportunistic or exploitative, benefiting from global inequalities. Petryna (2009) employs Foucault's theorization of power and subjectivity to argue that the globalization of clinical trials has reconfigured impoverished populations to be objects of governmentality and central to knowledge production and experimentation, a process she refers to as "experimentality" (30). And Farmer (2002: 1266) argues that transnational "research is a reminder that some populations are not really developing but rather are being left behind by the same economic processes that enable powerful [institutions] to do research in poor countries."

Although ethical codes for medical research have been modified to regulate how medical research is carried out, these codes have been difficult to apply in practice and have led to the rise of national and local oversight in the hopes that it might lead to equitable research collaborations. But these changes have not put to rest concerns about exploitation and inequality. These debates about and shifts in ethical regulation relate to a recognition of the wider global inequities in wealth and health. However, this broader context is generally considered outside the remit of medical research ethics. Instead, the focus has been on improving the individual rights of research participants and strengthening relationships between researchers and study communities. This includes expanding and improving informed consent procedures, as well as refining ethical guidelines and regulations, and tightening oversight of studies (Molyneux and Geissler 2008). Yet, the strengthening of the processes of review and refinement of guidelines may inadvertently depoliticize ethical debates and narrow ethical reflection. Additionally, the move towards the raising of standards has not always led to greater public trust and engagement. In fact, in Africa there has been a move towards transnational collaboration with Northern research institutions, over African national institutions, and use of high-end technologies that are protected inside research enclaves. This situation can lead to the strengthening of research capacity but creates challenges for building relationships with the public and local health systems. Refinement of ethical documents and greater oversight does not inevitably improve this situation (Molyneux and Geissler 2008; Geissler 2014).

There have been calls from scholars (Kelly 2011; Kelly et al. 2010; Jentsch and Pilley 2003; Molyneux and Geissler 2008; Gikonyo et al. 2008; Whyte 2011) to shift medical ethics beyond matters of standardization, regulation and written documents to consider the interests of populations, the role of research institutions, and the process of collaboration. This perspective emphasizes the recognition that research is carried out in an unequal world with disparities in wealth, and that research in this context includes vulnerable people who are not often able to experience the benefits of medical research, which includes the development of new drugs.

Geissler et al. (2008) explored these issues by researching a malaria vaccine trial in The Gambia conducted by the British Medical Research Council (MRC) from 2001 to 2004. From the perspectives of trial participants, many expressed their appreciation of the free medical care and a desire that the trial continue to provide material benefits after its end. People invoked the idiom of family when describing their relationships with trial staff. Although this kind of relationship was not represented in ethical codes or research protocols, it enabled the trial to operate. Gikonyo et al. (2008) found something similar during a malaria vaccine trial in Kenya. Most people the authors spoke to desired a form of recognition after the trial ended. Participation in medical research created new kinds of social relationships, which research staff played a key role in establishing and maintaining. Overall, the authors found that ethical standards were an inadequate response to complex and shifting ethical dilemmas in the field. Rather than focus on formal ethical standards, they argue that there needs to be greater attention to social relationships since they shape people's involvement in, and perceptions of, research. In another example, Kelly (2011) returned to the Gambian communities where Geissler et al. (2008) conducted research about a malaria vaccine clinical trial a few years earlier. She found that former trial participants desired connection and expressed a sense of disappointment at the discontinuation of health care services. The ending of the trial made it obvious that it had served the needs of researchers more than communities and that the trial had not lived up to its obligations to protect people's welfare. In this article, Kelly (2011) calls for the changing of scientific research protocols to focus on the production of social relationships between researchers and research participants over time, and that those relationships be held stable over time so they can lead to social progress.

From what these anthropologists found, expanding the meaning of research ethics to include a consideration of the needs of communities and placing social relationships at the centre of activities would be a way to acknowledge the importance of, and respect for, research participants and communities. This might include the provision of benefits, such as medical care infrastructure, provision of health care and ongoing social engagement, both during and after research ends. This expansion of benefits and increased engagement with communities are important aspects to consider when research is carried out in impoverished settings. These debates about ethics, social justice and inequality figure prominently in the narratives of my informants and will be returned to throughout the thesis.

Although the anthropologists above largely focused on the establishment of social relationships between communities and researchers from the perspectives of lay people, the experiences and perspectives of research staff are underrepresented in the literature. Molyneux et al. (2013) and Chantler et al. (2013) explored the roles of fieldworkers and village reporters in medical research to find they served as important intermediaries between communities and research institutions. Biruk (2012) also approached medical research from the perspective of research staff and discovered that the maintenance of social relationships between researchers and communities over time was essential, allowing for research to be conducted.

Building on this scholarship, this thesis focuses on the experiences, perceptions, and aspirations of staff working for the RTS,S vaccine trial in Tanzania, and brings in reflections from their Northern partners. Clinical trial staff were middle figures<sup>10</sup> that negotiated social relationships and partnerships with Northern institutions and companies, as well as communities and trial participants in Tanzania. These actors were involved in partnership to develop a technology, the RTS,S vaccine. Although the vaccine had already been invented in laboratories, it required testing outside of the laboratory to ensure it was safe and effective for widespread use. Hence, the vaccine was in a process of becoming. This process required technologies and material objects, which I describe throughout the thesis. But it was the social relationships, how people cared for, about and through

<sup>&</sup>lt;sup>10</sup> This term is borrowed from Hunt's (1999) analysis of nurses, assistants and servant who provided medicine in the Belgian Congo during colonialism. As she argues, paying attention to these middle figures shows how global practices are negotiated and translated in specific contexts, times and places.

technologies, the exchanges of material objects between actors, and the moments of affect, including doubt, joy, frustrations, misunderstandings, and connection, that were of key importance in the vaccine's becoming. It is these aspects that are central to this thesis.

Reflections on these aspects of medical research were particularly meaningful at the end of the RTS, S partnerships and vaccine trial. This was a time that was laden with reflections on the past, present and future as people tried to understand their involvement in the development of the vaccine and the impacts of the trial and partnerships on Tanzania. My research at this time brought forth various narratives, including people's expectations and aspirations, which is an imaginary of the future that often is left out of institutional readings of partnership. Global inequalities, hierarchy and unequal power relations also formed part of people's reflections on the partnerships, as did the many exchanges between institutions and people, which shaped social relationships between actors. Additionally, practices of care were central to people's narratives and actions. Although critical analysis of global health partnerships and science is necessary in a stratified world, de la Bellacasa (2011) argues for a feminist theory about science and technology. She calls for an analysis of care in technoscience since science requires care and affective labour to bring things like vaccines into being. Care is a largely dismissed and undervalued form of every day labour but as de la Bellacasa states, "nothing holds together in a liveable way without caring relationships." (100) I draw on this theory of care to highlight that people put affective labour and care into their social relationships with partners, research participants and communities and they extended this care to the maintenance of scientific and technological systems. In this context, care for human bodies, social relationships and material objects was not simply carried out to maintain ethical protocols, it was central to how informants perceived their jobs and the value of the RTS,S partnerships and vaccine trial.

What held all of these aspects together—despite acknowledgement of inequality and provision of a tremendous amount of affective labour on the part of trial staff—was a desire to be involved in creating a technology that has the potential to save many African lives. This desire helped trial staff to conceptually overcome issues of inequality between Northern and Southern partners, and researchers and communities in Tanzania. In this thesis, I examine the materiality, social relationships, power dynamics, practices of care, and exchanges on the local and

global scales, and explore the varying impacts and interpretations of partnership and scientific activity in Tanzania as they came to an end. I now turn to a discussion of my research methodology and field sites, as well as the ethical issues encountered over the course of the research.

## Methodology, Field Sites and Ethics

This thesis traces the development of the RTS,S malaria vaccine as a way to understand broader issues in global health and transnational medical research. RTS,S was developed in the US and Belgium and tested in clinical trials in the US, Asia and across Africa. Its development involved a number of research institutions, companies, non-profit organizations, researchers, doctors, fieldworkers and research participants. From 2009 to 2014, a phase 3, double blinded, randomized control trial of RTS,S, was conducted across Africa to assess the efficacy of the vaccine to prevent malaria. Eleven trial sites were chosen in seven African countries: Tanzania, Mozambique, Malawi, Kenya, Gabon, Ghana, and Burkina Faso. The trial enrolled over 15,000 children in two age groups: a younger group aged 6 to 12 weeks and an older group of 5- to 17-month-old children (Cohen et al. 2010; RTS,S Clinical Trials Partnership 2015).

To get a better sense of this global technology and partnerships, I employed a methodology that many anthropologists use to explore multi-sited objects—a "follow" the thing, ideas, people and so on—approach (Marcus 1995). Thus, I conducted ethnographic research in Africa and Europe, with additional interviews conducted via internet video calls. I centred my ethnographic research on a RTS,S trial conducted in the town of Korogwe, Tanzania. There, a building, the Korogwe Research Centre<sup>11</sup>, was designed by the Danish architect, Jakob Knudsen (Napier 2017).

The Research Centre held several offices, two laboratories, two conference rooms, a pharmacy, and data management and archival space. It was situated across a parking lot from the Korogwe District Hospital, which was nicknamed *Magunga* for the sisal estate that used to be located there. The Korogwe Research

<sup>&</sup>lt;sup>11</sup> The full name of this building is the NIMR Korogwe Research Laboratory but in order to denote that this building is more than a laboratory, I refer to it as the Korogwe Research Centre throughout this thesis.

Centre served as the central site for the vaccine trial and my ethnographic research. Additionally, eight dispensaries were built and one government-run dispensary was refurbished in villages in rural parts of the Korogwe and Handeni Districts so that trial participants could be vaccinated close to their homes. These dispensaries served the 34 villages involved in the RTS,S trial and were additional sites for my research.

Fieldwork for my doctoral project began in November of 2012. Previously, I conducted ethnographic research about the human papillomavirus, or HPV, vaccine. The entry of this new vaccine on the market had sparked my interest during my undergraduate studies and after writing a paper on the HPV vaccine for a medical anthropology class. I entered a Master's degree program in social anthropology to study HPV vaccine uptake amongst university students in Canada. I had planned to conduct ethnographic research about this vaccine as it was being provided to school-aged students in Tanzania. However, I conducted pre-fieldwork research in Tanzania in April of 2012 and learned from a policy maker in the Tanzanian Ministry of Health that the program had insufficient funding and would likely only begin in 2014. This policy maker suggested I instead study the RTS, S malaria vaccine being tested in Korogwe and Bagamoyo, Tanzania. I connected with the Principal Investigator (PI) of the RTS,S clinical trial in Korogwe and after meeting with him, he welcomed me to conduct ethnographic research at the vaccine trial site. I took him up on his offer. During that trip, I also had an opportunity to tour the Korogwe Research Centre and speak with Simon, the site coordinator at the Research Centre, and attend a medical research conference in Arusha to meet several RTS,S trial staff members. This laid the ground work for my doctoral research.

Before I returned to Tanzania to conduct research in late 2012, I applied to become an ancillary researcher of the RTS,S trial, a requirement for access to the clinical trial site in Korogwe. I was obligated to sign a document that I submitted to the Ancillary Study Review Committee (ASRC), a committee formed by GSK, MVI and the clinical trial sites, which oversaw research conducted about the third phase of the RTS,S clinical trial. At the time, I was troubled by the thought of signing this document because it required that I provide GSK and MVI access to my recordings and allowed these organization to review and comment on publications of my results. I signed the document in order to carry out my research and to this day, I have not been asked to provide data to GSK or MVI. As well, these organizations

have reviewed two manuscripts I have sent out for publication and have not had issues with them.

In September of 2012, I passed an ethical review of my research proposal at the University of Edinburgh and applied for research clearance from the Tanzania Commission for Science and Technology (COSTECH). By the time I arrived in Tanzania, I had received research clearance from COSTECH. I then submitted my application to NIMR for medical research clearance. I was reassured by staff at NIMR that this step would take a month or two. After waiting for four months, my local supervisor, Dr. Peter E. Mangesho, visited the NIMR headquarters with me to inquire why it was taking so long for my application to be reviewed. NIMR staff said they would make a speedier decision about my application and a month later my application was approved and I received clearance to conduct medical-related research. Upon receiving this clearance, I applied for a Tanzanian research visa, which took almost three months to be issued. In total, it took eight months to pass ethical review and receive a research visa.

Waiting so many months to commence research was frustrating. However, I used this time to study Swahili in Dar es Salaam and in Stone Town, Zanzibar. I also spoke informally to people I met in my day-to-day life in Dar es Salaam and Zanzibar. This included lay people (including Tanzanians and expatriates); doctors, nurses and an herbalist; researchers at NIMR and Muhimbili University of Health and Allied Sciences; and malaria policy makers and program managers at global health organizations (including the Clinton Health Access Initiative (CHAI), the Global Fund and US Centers for Disease Control (CDC)). I attended an annual trade fair in Dar es Salaam during the holiday of Saba Saba. There, a pavilion dedicated to malaria had been set up and I spoke to parasitologists and pharmacists who were providing information to lay people about how to protect themselves from malaria. Additionally, I attended a medical research conference in Arusha in April 2013 in order to meet researchers and learn about medical research conducted in the country. All of these interactions helped me gain an understanding of how malaria was being prevented and treated in Tanzania, how lay people understood, experienced and treated malaria and how the health care system operated. Additionally, although I had learned guite a bit about malaria before starting fieldwork, there was still more for me to understand so to I read widely about malaria and control measures. My reading included scientific articles and editorials, as well as archival material housed in the building where the National Malaria Control

Program (NMCP) was located in downtown Dar es Salaam, which held records about past control programs. Throughout, I took copious fieldnotes about what I was learning, which helped me refine my research questions and interview protocols. These activities also helped me build research contacts, which allowed me to hit the ground running as soon as I was able to conduct research.

Also, this period allowed me time to immerse myself in the local context and become comfortable with living in Tanzania. That process served me well as I interacted with informants after gaining research clearance because I could greet people in Swahili, had some knowledge about Tanzania, and was able to ask more informed questions. Many people I came in contact with expressed surprise upon learning how long I had been living in the country because they regularly interacted with foreign researchers who visited the country for very short periods of time. For some, my length of stay demonstrated that I was serious about understanding malaria in Tanzania and I believe this led to better interactions and interviews. Overall, this period, while unexpected, enriched my understanding of a range of topics, including malaria, health care provision and Tanzania.

Once I received a research visa, I conducted nine months of ethnographic fieldwork in Tanzania from August 2013 to April 2014, with additional in-person and video call interviews carried out until June 2015. Although not the direct focus of this thesis, I conducted semi-structured interviews with a range of people involved in malaria research and control. These included donors at PMI, RBM and the Global Fund; policy makers at the NMCP, the WHO, the Ministry of Health and the CDC; researchers at Muhimbili University and NIMR; and partnering organizations that implemented malaria control programs in Tanzania, including RTI International, CHAI, Jhpiego, the U.S. President's Emergency Plan for AIDS Relief (PEPFAR), Swiss Agency for Development and Cooperation (SDC), John Snow, Inc. (JSI), Population Services International (PSI), Communication and Malaria Initiative in Tanzania (COMMIT), and PricewaterhouseCoopers (PwC). I also attended several meetings between PMI, the CDC, the NMCP, and implementing partners as they discussed funding priorities and results from PMI-funded control programs and research projects. All of these activities provided valuable insights into the politics surrounding global health and malaria control on the global scale and how these politics played out on the ground in Tanzania. Gaining these insights proved helpful for my research in Korogwe.

In November of 2013, I arrived in Korogwe, a town in north-eastern Tanzania where the third phase of the RTS,S clinical trial was being conducted. The town of Korogwe is situated within Korogwe District, in the Tanga Region. As of the 2012 Tanzanian population and housing census, the town of Korogwe had a population of 68,308 and Korogwe District had a population of 242,038. Korogwe is a road junction that connects the cities of Dar es Salaam and Arusha and is located 280 kilometres from Dar es Salaam, 340 kilometres from Arusha, and about 100 kilometres inland from Tanga town on the Indian Ocean.



Figure 1: Map of Tanzania and location of Korogwe (Coe 2006).



Figure 2: A close up of the districts of Tanga Region with Korogwe District highlighted and Handeni District below (Coe 2006).

Korogwe District is in a tropical area and has two rainy seasons, one from October to December and another from March to May, although climatic changes in the last decade at times merge these two rainy seasons. Malaria is most often transmitted during the rainy season(s). Temperatures range from 18°C to 30°C. Many people reside in rural settings and practice informal trade and subsistence farming, mainly growing rice, coconut, banana, cassava, maize and oranges (Mahende et al. 2014; Mmbando et al. 2010). Sisal production has been ongoing in Tanga Region since being introduced in 1893 by the German East Africa Company. Many sisal plantations are still in operation, employing many people in the region (Giblin and Giblin 2005; Kimaro, Msanya and Takamura 1994). In addition to the Korogwe District, the phase 3 RTS,S clinical trial was also conducted in villages in Handeni District, to the south of Korogwe District. As of the 2012 National Census, Handeni District had a population of 276,646 (National Bureau of Statistics 2013; Mahende et al. 2014; Mmbando et al. 2010). Most people engage in subsistence farming in Handeni District (Shabani et al. 2015).

Korogwe District has one district-level hospital, two church-owned hospitals, four health centres and 47 government dispensaries. Annually, the Korogwe District Hospital receives about 6000 children under five years of age, as of 2010 estimates (National Bureau of Statistics 2013; Mmbando et al. 2010; Mahende et al. 2014; Kahabuka et al. 2012). Korogwe District is stratified into highland and lowland zones and altitudes range from 300 to 1,200 metres above sea level (Liheluka, Lusingu and Manongi 2013). There has been ongoing research about falciparum malaria in Korogwe District and this research has detected that the rates of malaria in highland villages has decreased from 25% in 2003 to 3% in 2008, and in lowland villages it has decreased from 78% to 13% (Mmbando et al. 2010). Despite this decrease, children under the age of five admitted to the Korogwe District Hospital are most commonly diagnosed with malaria, anaemia, pneumonia, diarrhoea, septicaemia and gastroenteritis (Mahende et al. 2014). It is in this setting that the RTS,S vaccine trial was conducted.

Once I received the official documents to conduct my research, I arrived six weeks before the end of the RTS,S clinical trial. These documents were important to obtain because when I arrived at the Korogwe Research Centre, trial administrators asked for these documents and took photocopies of them to keep on file. Only once they were satisfied that I had acquired correct documentation did they fully welcome me to conduct my research.

After these formalities, Simon, the site coordinator, gave me a tour of the Research Centre and introduced me to staff. Simon explained to them that I was a PhD student from the University of Edinburgh, that I would be conducting research on trial activities and would want to interview people during my time in Korogwe. This introduction was helpful to inform staff of who I was and what I was doing there and most staff were very friendly and welcoming. However, I felt uncomfortable having someone in a superior position tell staff that they should welcome me and consider being interviewed since I was concerned staff would feel they had little choice in being involved in my research. To help counter this, at the time I clarified with staff that I would be interested in interviewing them but only if they wanted to be involved. But I was still concerned about people's inability to opt out of being studied since I was observing and interacting with them at their place of work.



Figure 3: The Korogwe Research Centre.

Due to these concerns, I was hesitant to observe staff as they worked when I first arrived in Korogwe. Instead, for the first few days I conducted semi-structured interviews. I asked staff in person if they were willing to be interviewed in their office or in one of the conference rooms at the Research Centre, which informally served as my office when it was unoccupied. Many staff were willing to be interviewed and before each interview a consent form was provided in English and Swahili. Each was asked their permission to be interviewed and recorded and all agreed. All interviews were conducted in English and lasted from 30 to 70 minutes in length. I

conducted a majority of my interviews with staff in the first week of my time at the Research Centre. These interviews provided insight into trial activities and helped me to develop rapport with staff. Many whom I interviewed invited me to observe them working and that is when I felt comfortable to conduct participant observation of trial activities.

In the last six weeks of the trial staff were carrying out activities to complete the trial. This included visiting the homes of trial participants to collect health information; collecting biometric data, medical histories and blood samples from trial participants; and conducting preliminary analysis and preparation of blood samples and data to be sent abroad. Joining in on these activities, I observing how staff carried them out and at times I helped with tasks, such as moving supplies or files. These times provided opportunities for casual conversations about their thoughts on the work and those they came in contact with over the course of their work days. This participant observation was conducted in the laboratories and data management offices at the Korogwe Research Centre and the trial dispensaries in villages in Handeni and Korogwe Districts. In addition, observation was carried out in the pediatric ward of the Korogwe District Hospital, where health care was provided to children under the age of five, including RTS,S trial participants. While in the hospital ward, activities were observed as children arrived with caregivers<sup>12</sup> and were given vaccines, diagnosed or had blood samples drawn, and treated for illness. As this was ongoing, I spoke to nurses and doctors about how the hospital ward functioned and the role of the RTS,S trial in funding health care provision there. I also met with nurses, clinic officers, doctors and laboratory technicians who worked for the Korogwe District Hospital and government dispensaries that were located near trial dispensaries. I was given tours of these health care facilities and government staff discussed their jobs and the Tanzanian health care system with me.

While in Korogwe, I stayed in a guesthouse funded by ENRECA, a University of Copenhagen longitudinal study about malaria rates in Korogwe District. This guesthouse intermittently housed a couple of Tanzanian and international researchers and a few RTS,S trial staff who did not permanently live in Korogwe.

<sup>&</sup>lt;sup>12</sup> I have chosen to use the word 'caregiver' in place of parent because, although a majority of the adults who cared for trial participants were biological parents, in some cases, grandparents, siblings, relatives and others provided care to trial participants.

Staying at this guesthouse allowed me to build rapport with researchers and staff and engage in informal conversations during non-working hours.

I left Korogwe in late December and returned to Dar es Salaam, where I maintained an apartment. In early January, I returned to Korogwe to conduct two more weeks of research. At this time, interviews were conducted with staff that had been missed during the previous visit and a second interview was carried out with a trial administrator. Participant observation was also conducted at trial and government dispensaries, the pediatric ward of the Korogwe District Hospital, and the Korogwe Research Centre as staff wound down the trial.

In addition to research amongst RTS,S trial staff, I also carried out semistructured interviews with a range of other people involved in the development of the vaccine, including vaccine scientists and trial funders/coordinators. When I was in Dar es Salaam in early January 2014, I interviewed via internet video call a British malaria researcher and co-PI of a West African RTS,S trial who was in the UK at the time. While in Dar es Salaam in February 2014, I jointly interviewed two RTS,S scientists from GSK in Belgium. One day in March 2014, I visited the RTS, S clinical trial site in Bagamoyo, a town north of Dar es Salaam, to speak to the site coordinator and get a tour of the facilities. This gave me a better understanding of how this branch of the trial operated, which served as a point of comparison to the Korogwe branch of the trial. After returning to Edinburgh, I jointly interviewed two representatives of MVI in the US over internet video call. These interviews ranged from 40 to 70 minutes in length. Additionally, I interviewed the co-inventor of RTS,S twice; once via telephone in early January 2014 when I was in Dar es Salaam and he was in Belgium and the second time in person when I visited GSK Biologicals in Rixensart, Belgium in May 2015. Meeting the co-inventor in person allowed for informal discussion before and after the interview as well as a chance to see where the RTS,S vaccine had been invented and manufactured.

Although trial participants and caregivers are not the direct focus of this thesis, I interacted with them as trial activities were being conducted. One day I visited the homes of two trial participants after their mothers invited me. This experience was enriching but limited. The trial fieldworker I was with did not feel comfortable with the questions I had of caregivers and cited trial protocols for the reason I could not ask about their experiences of the vaccine trial. Though approaching the RTS,S vaccine trial from the direction of the trial staff provided access to trial activities and staff, it made my access to other people who had been

impacted by the trial more difficult. However, as Okwaro and Geissler (2015) argue, a large amount of anthropological research has been conducted amongst communities and research participants of medical research (see, for example, Geissler et al. 2006; Geissler 2005; Kelly et al. 2010; Fairhead et al. 2006; Leach et al. 2008; Leach and Fairhead 2011; Marcis 2015). The world of science, including the views and experiences of African scientists, has received little attention. This thesis builds on the work of anthropologists, such as Okwaro and Geissler (2015) and Crane (2013), by focusing on the people conducting medical research, including African scientists.

Although most people I came in contact with through the course of research were friendly, some were unwilling to be interviewed. I respected those decisions and never pushed people to be involved in my research. Some staff at the Korogwe Research Centre appeared suspicious, concerned or uncomfortable with my presence at first, especially those working in the data management office. It was unclear to me why a couple of those staff members in particular responded to me in that manner. However, they experienced regular auditing from Quintiles, a USbased Contract Research Organization, which ensured adherence to ethical and regulatory guidelines. I wondered if these staff felt I was there to evaluate their performance and therefore did not feel comfortable around me. I gave these people space and found most staff I interacted with eventually grew comfortable with my presence, even if they remained unwilling to be interviewed. I found something similar amongst policy makers in Dar es Salaam. Some were unfriendly or suspicious at first but when I showed that I had gained ethical clearance and asked questions about topics they were interested in, they warmed to me and gave me generous amounts of their time. Only one policy maker was uncomfortable with being voice recorded and requested that I only take hand written notes. In some cases, language might have been an issue in people's involvement in my research. Although I learned sufficient Swahili to converse with people in my day-to-day life, I did not gain sufficient proficiency to conduct interviews about science, malaria and vaccines. Those staff less confident in their English skills may have felt uncomfortable to be interviewed in English.

Additionally, my positionality, including my age, gender, level of education, and status as a *mzungu* (foreigner) shaped relationships with people I encountered over the course of fieldwork. In some ways, my status and level of education endowed me with symbolic power that helped me gain access to people and places.

At the same time, my gender and age meant that some acted in a superior manner and wanted to teach me things. Although this was frustrating at times, it was also helpful because those people seemed more than happy to share their knowledge, experiences and thoughts about malaria, the RTS,S trial and other topics with me.

While conducting research and writing this thesis, I have been concerned with respecting my informants' rights to privacy and anonymity. At times, I had issues with gaining fully informed consent, due largely to the dynamic nature of anthropological research conducted in many contexts with a range of people, and difficulties in communicating the meaning of my research. However, I always explained who I was and my research when I met people in the course of fieldwork. And during formal interviews I provided consent forms, which included information about myself and my project, and required a signature indicating agreement to be interviewed. Thus, to my knowledge, those included in this thesis were aware of their role in my research.

Throughout the thesis, I have used pseudonyms for all informants except the co-inventor of the RTS,S vaccine. He is a public figure and there was no easy way for me to share his very particular thoughts and experiences without identifying him. He consented to being identified in this thesis. For all other informants, I use pseudonyms but this does not guarantee anonymity. Those involved in malaria control in Tanzania or developing the RTS,S vaccine are part of small communities and often have distinct roles. This situation may make it possible for those in these communities to discern who has been involved in my research. For many informants, I have been vague in describing their position but in some cases I have been more specific in order to demonstrate their position within institutions. Each of these people is aware of the nature of my research and have signed a consent form to have their interviews included in the thesis. Below, I provide a summary of the chapters of the thesis.

## **Chapter Summaries**

This thesis is divided into five chapters. The first chapter is titled, "Productive Partnerships". This chapter provides a history of malaria vaccines and the RTS,S vaccine, as well as the various actors and organizations that have played roles in the development of RTS,S over time. I argue that partnership and other forms of social relationship have made vaccine development possible. During the late stage clinical trials in Africa, these partnerships occurred in situations of stark inequality between actors and places. Through recollection, several informants portrayed these partnerships as equal. However, it was difficult for them to not reference inequalities between Northern and Southern actors. In this chapter, I present an analysis of informants grappling with this contradiction.

Chapter Two, entitled "Perceptions of Success", charts informant's reflections on the partnerships and RTS,S clinical trial as these were drawing to a close and after they had ended. As informants thought about the beginning and end of the trial, they described several aspects of partnership and trial activity as successful. This included the building of research capacity and human capacity, the provision of health care, mosquito nets and health education, and the fostering of relationships with communities. I draw on Mosse's (2005) theorization of projects to argue that informants perceived the partnerships and trial a success because they were drawn into an "interpretive community", meaning their ambitions, goals and desires were being successfully addressed through the development of RTS,S. At the same time, informants may have desired to affirm to themselves that they had been involved in a successful clinical trial.

Chapter Three, "Building a Legacy?", explores the materials and technologies that enabled the RTS,S partnerships and clinical trial, including research and health care infrastructure and buildings, laboratory equipment, and communication technology. These material objects were symbolic of the transnational partnerships, were important parts of the exchange between Northern and Southern institutes and were perceived by informants as lasting impacts of the partnerships and trial on Tanzania. Trial staff cared for these material objects throughout the trial and after the vaccine trial had ended. This caring labour was a way to provide maintenance but staff also desired to care for gifts given to them by their Northern partners. Yet, their Northern partners had no such sense of obligation once the partnership ended. These objects experienced decay and trial staff expressed a sense of loss but staff continued to provide care to these objects because they held the potential for future partnership.

The fourth chapter is titled "The Boundaries of Care". The RTS,S clinical trial provided health care in parallel to and from within the Tanzanian public health care system. There were many exchanges of resources and information between the two health care providers. Through these exchanges, the division between the

public and private health care system were reinforced and this division became even more obvious after the vaccine trial concluded. I examine the spatial organization of the two services, informant's perceptions of these two forms of health care, and the exchanges between the two. I argue that the private provision of care shaped people's ideas of how a public health care system should operate and led to feelings of loss and frustration at the inability of the vaccine trial to enact lasting change on the public health care system. Thus, the long-term impacts of the vaccine trial were not only material but also ideational.

Chapter Five, "Blood and Paper", traces the collection, analysis and movement of evidence about the RTS,S vaccine, which materially came in the form of blood and paper. Blood and information recorded on paper were collected from trial participants, moved to the Korogwe Research Centre, analyzed in a preliminary fashion, prepared for transportation, and moved out of Tanzania for further analysis. This was a process of abstraction but the actual labour that went into this process was anything but abstract. Trial staff provided care to participants and sought to connect with participants in order to make evidence collection run smoothly. The collection of evidence involved exchanges of bodily tissue, information, and time as the social relationships between trial staff and research participants were challenged and reaffirmed through affect, care and the provision of material resources. Although these components of the vaccine trial are not represented in the final analysis of the vaccine, I argue that these enabled the RTS,S vaccine to be developed.

# Chapter 1: Producing Partnerships: An Account of RTS,S Malaria Vaccine Development and Partnerships

## Introduction

With shifts in institutional organization, improvements in bio-technology and the establishment of partnerships, the RTS,S malaria vaccine was developed over a more than 30 year period. In order to understand the development of RTS,S, I interviewed Dr. Joe Cohen, the co-inventor of the vaccine. I first interviewed him via telephone in February 2014 when I was on fieldwork in Tanzania. At the end of that interview, Dr. Cohen invited me to visit him at GlaxoSmithKline (GSK) Biologicals headquarters in Rixensart, Belgium, outside of Brussels. I took him up on that offer and travelled to Rixensart in May 2015 to meet him in person for a follow-up interview and see GSK Biologicals first hand.

GSK built its vaccine research facilities on expansive grounds in the small town of Rixensart. It was there that the RTS,S vaccine was invented and subsequently manufactured before being sent to Tanzania for the phase 3 RTS,S clinical trial. When I was in Korogwe, GSK Biologicals felt like a far away and mysterious place. The data collected in Tanzania was sent there, as the Korogwe Research Centre received regular enquiries from researchers in Rixensart, which were answered by data managers in the basement of the Korogwe Research Centre. But those exchanges were entirely mediated by computers, the internet and a satellite connection, creating a clear separation between Tanzania and Belgium. Visiting the place where the vaccine was created and data was sent helped me to conceptually connect the two places.

Arriving in the tiny town of Rixensart in the afternoon after taking a train from Brussels, I walked to the outskirts of the town where GSK Biologicals was hidden behind trees in a quiet residential neighbourhood. Passing through two security checks, I met Dr. Cohen in a large building that held the offices of vaccine developers. Dr. Cohen had white hair and a grey beard and was dressed casually in slacks and a collared shirt. Greeting me, he led me upstairs to a meeting room. Along the way, I caught sight of a large promotional banner that had Dr. Cohen's stern face on it and the quote: "Malaria is relentless. But so is Joe Cohen" hanging from one of the suspended walkways above our heads.

We spoke in an over-lit meeting room and Dr. Cohen shared the story of how RTS,S was developed, including the various partnerships, actors, institutions, technologies and research techniques that came together to enable its creation. To better situate this story, I first provide background on the history of malaria vaccines. Second, I draw on my interviews with Dr. Cohen and secondary literature to trace the history of the RTS, S malaria vaccine from its birth in laboratories, to its clinical trials, and evaluation for use across Africa, examining how researchers built upon existing scientific understandings of vaccines and immunology to employed new tools and techniques. Through the retelling of this history, I also uncover the various partnerships formed to support vaccine development and describe how resources and expertise were mobilized to confront health risks and create capital. Third, I examine the partnerships and collaborative relationships established late in the development of RTS,S, during its phase 3 trials across Africa. These partnerships were among diverse actors, with each bringing varying levels of resources and expertise to the table. Despite claims of equality and mutually, informants could not avoid referencing hierarchal and unequal power relations between Northern and Southern actors. I explore people's narratives as they contend with that contradiction. This discussion lays the groundwork for the rest of the thesis where I explore how these hierarchies and differences impacted people's perception of the RTS,S trial and partnerships. Below, I provide a summarized history of malaria vaccines.

#### The History of Malaria Vaccine Development

Malaria and the mosquitoes that carry it have often thwarted intervention (PATH-MVI 2016; Doolan, Dobaño and Baird 2009). From the development of quinine, chloroquine, bed nets, DDT, artemisinin and other preventative and treatment methods, malaria and the mosquitoes that carry the parasite have found ways to adapt and overcome them. Given the impact of malaria on millions of people and the decreasing efficacy of current control methods, the development of an effective malaria vaccine is high on the global health agenda (Shah 2010; Packard 2007; Sherman 2009).

For decades, researchers have attempted to develop a vaccine for malaria. Malaria researchers have observed for centuries that people native to malaria endemic regions have a level of immunity to the parasite. Building on that knowledge, malaria vaccine researchers have made use of increasingly sophisticated scientific tools over time to create efficacious vaccines that target various stages of the malaria life cycle. A vaccine functions by exposing the body to a weakened version of a virus, bacteria or parasite before the body becomes exposed to a fully functioning version. This exposure can help the body develop immunity to these pathogens and decrease the severity of complications associated with infection. Thus, the aim of developing a malaria vaccine is to help people build immunity to malaria without them having to suffer from the ill effects of the disease. An effective vaccine could lower the number of malaria infections amongst children and the general population, decreasing the number of people suffering and dying from the disease, and play a role in eventually eradicating malaria (NIH 2008; Packard 2007; Shah 2010; Desowitz 2002; Sherman 2009).

However, although there have been many attempts to develop a malaria vaccine, few have been efficacious. Malaria is unlike other diseases because becoming infected with malaria does not lead to full immunity to later infections. This means that if someone falls ill from malaria and recovers, they can be infected all over again. There is a degree of acquired immunity: a person who has had malaria in the past can become infected again but likely experience less severe symptoms. This partially acquired immunity only builds from repeated infections but can be lost if the person moves away from a malaria transmission area for a year, leaving them as vulnerable as someone who has never had malaria. This situation makes the development of a vaccine more difficult since administering a vaccine may not lead to lasting protection over time. Some researchers have cautioned that a vaccine may not be any better than naturally occurring immunity that develops after repeated infections with malaria (Sherman 2009).

Despite the mechanism of illness for malaria being discovered in 1880, it has taken over a century to develop an efficacious vaccine (IAVI 2008; RTS,S Clinical Trials Partnership 2015). Since the 1800s, researchers have worked towards understanding the life cycle of the *Plasmodium* parasite and the human immune responses to it. During this time, researchers have also developed vaccines and drugs through field and laboratory research. Ideally, research should have been conducted with the *Plasmodium* parasites that infect humans. However,

researchers chose non-human animals for malaria studies due to the safety and ethical concerns of using human subjects, the limited availability of human subjects, and the difficulty of growing *Plasmodium* species in a laboratory or in other animals. These surrogates, which included rodents, monkeys and birds, were less than ideal because a different malaria species infects each of these animals and each animal has different biological mechanisms for immunity. Thus, a successful vaccine for a rodent, monkey or bird is unlikely to offer protection for humans. This meant that for decades, research in non-human animals was difficult to correlate into creating a vaccine for humans. However, studies on non-human animals allowed researchers to understand broadly how malaria operated in the body of its host and theorize about various ways to target the different life cycle stages of the parasite (Sherman 2009).

At the height of the malaria eradication program in the 1950s and 1960s, the scientific community was not conducting malaria vaccine research. At this time, control efforts focused on DDT and drug treatment and a malaria vaccine seemed unnecessary and extravagant (Desowitz 2002; Sherman 2009). The World Health Organization (WHO) and United States Agency for International Development (USAID) declared that they would not pursue a malaria vaccine, stating that, "failure will continue to be the norm rather than the exception." (Shah 2010: 167) However, eradication efforts stalled and reversed as surveillance methods relaxed, some countries experienced turmoil, and resistance to drugs and chemical sprays grew. A malaria vaccine became a possibility in 1961 when Sydney Cohen and Ian McGregor found that administering blood from immune Gambian adults to children infected with *P. falciparum* led to anti-parasitic effects. This indicated that in theory, malaria vaccination was possible. Blood from immune Gambian adults was also able to treat children with malaria in Tanzania. This suggested that African strains of the parasite were similar and that a vaccine prepared against malaria in one region of Africa could be effective against malaria in another region (Sherman 2009).

Although countless amounts of blood have been collected from many thousands of people, it is still not entirely understood how the malaria parasite operates inside its human and mosquito hosts and why immunity in humans last such a short period. However, many researchers have been able to devise vaccines that disrupt the three different stages of the malaria life cycle. Using nonhuman primates, different formulations of 'antigens' (a molecule able to induce an

immune response) and 'adjuvants' (a chemical that boosts the effect of a vaccine) have been devised. The aim is to stimulate the body to produce 'antibodies', proteins that neutralize pathogens such as parasites or viruses. Although not a perfect match to humans, these studies have still helped move malaria vaccine research forward. Additionally, genetic-immunological technology has become increasingly sophisticated, helping scientists target the genes of the parasite and create better vaccines (Lee and Nguyen 2015; NIH 2008; Desowitz 2002; Sherman 2009).

Various malaria vaccines that target different life stages of the malaria parasite are currently being developed in laboratories around the world. One kind of malaria vaccine targets the first stage of the malaria infection and is called a 'preerythrocytic' vaccine. At the first stage of malaria infection, mosquitoes inject 'sporozoites' (the name for early-stage malaria parasites) into the human host, which then invade the liver, initiating the malaria infection (Vekemans et al. 2009). When sporozoites are injected into the host, the number of parasites is relatively small. A pre-erythrocytic vaccine helps the body to develop antibodies to prevent the parasite from either entering the liver or multiplying in the liver. Although most other vaccines of this kind of have not been successful, the RTS,S malaria vaccine is a pre-erythrocytic vaccine that is efficacious (Greenwood and Targett 2011; Sherman 2009; Girard et al. 2007). I will provide a detailed history of how researchers developed this vaccine in the upcoming section of this chapter.

Researchers have also created vaccines that target the malaria parasites after they leave the liver and are entering the red blood cells of the human host in order to multiply. These are called 'erythrocytic stage' or 'blood stage' vaccines and build on what Sydney Cohen and Ian McGregor found in 1961 when they transferred blood from malaria immune Gambian adults to children who had malaria. Vaccines that target this stage either attempt to induce an immune response that blocks invasion of the parasite into blood cells or inhibits their multiplication. An example of blood stage vaccine was SPf66, which was developed in Colombia by Dr. Manuel Patarroyo. In the early 1990s, SPf66 was tested in a phase 3 randomized control trial with children and infants. While protection from malaria was found in experiments on non-human animals, clinical trials in Tanzania, Thailand and The Gambia were disappointing and researchers stopped the development of the vaccine. Many alternate versions of blood stage vaccines are currently being developed (Greenwood and Targett 2011; Alonso et al. 1994; Girard et al. 2007).

'Transmission blocking' vaccines are another kind of malaria vaccine. They do not protect the person vaccinated but works by stopping people who have malaria from transmitting it to others. A transmission blocking vaccine works by having the human host generate antibodies against the malaria parasite. These antibodies are then transmitted along with the malaria parasite into a female mosquito when that mosquito feeds on a vaccinated person. When the malaria parasites begin to sexually reproduce in the mosquito midgut, the antibodies produced by the previous host attacks the parasite (Sherman 2009; Greenwood and Targett 2011; Girard et al. 2007). Since mosquitoes only fly less than 1 kilometre, people administered with this vaccine would be helping prevent malaria in their families and communities. That is why some call this an altruistic vaccine. The scientist Richard Carter devised the idea of this vaccine in 1974 when he realized that other kinds of vaccines would not be 100% effective, allowing malaria to continue its transmission. Studies on a transmission-blocking vaccine in mice have demonstrated a high efficacious rate, decreasing the number of malaria parasites by 97% and the number of malaria infected mosquitoes by 75% (Sherman 2009). Early stage clinical trials of this vaccine indicate it is over 90% efficacious in preventing malaria in humans and larger-scale trials are currently ongoing in Africa, Europe and the US. However, in order to manufacture this vaccine, the salivary glands of mosquitoes must be dissected to obtain living malaria parasites. This labourintensive form of manufacturing may impede development of this vaccine (Seder et al. 2013; Richie et al. 2015; Hoffman et al. 2015)

There are other kind vaccines that have been theorized and tested on nonhuman animals but the three kinds of vaccines described above are the most advanced. Much research has involved both humans and non-human animals, and countless numbers of mosquitoes, malaria parasites, and human blood samples have been studied in the pursuit of a vaccine. A few vaccines appear promising and some people have prophesized that a malaria vaccine will arrive quickly. As Sydney Cohen and Ian McGregor proclaimed when devising their blood stage vaccine in 1961, "An experimental vaccine … may be only a decade away … and if it is very effective malaria will be eradicated like smallpox" (Sherman 2009: 319). However, a fully effective malaria vaccine still remains elusive, decades later. Even with the RTS,S vaccine, existing malaria control measures will need to be employed in order to effectively prevent malaria (RTS,S Clinical Trials Partnership 2015). Malaria is a highly complex organism with 5,300 genes that code for *P. falciparum* strains, half of

which have no known function or counterpart in other living creatures. As well, malaria has a complex life cycle that involves both a vector and a host (Sherman 2009). Research teams are attempting to combine different kinds of vaccines to create one vaccine that targets different stages of the malaria life cycle but it may be many years until a highly efficacious malaria vaccine is available (Sherman 2009; Girard et al. 2007).

#### **RTS,S Vaccine Development in Laboratories**

Although the previous section provided an overview of malaria vaccine development, I now focus on the development of the RTS,S malaria vaccine. This new technology was created with the use of new scientific knowledge and ideas of immunology and prevention, as well as new business models and transnational partnerships. Describing the invention and development of RTS,S over time, I elucidate the shifts in scientific knowledge and global partnerships that have made this vaccine possible, drawing on my interviews with the vaccine co-inventor Dr. Joe Cohen and secondary literature.

When I interviewed Dr. Joe Cohen in a meeting room at GSK in Rixensart, Belgium in 2015, he spoke about the development of RTS,S and its potential future impacts in sub-Saharan Africa. By that time, RTS,S had been tested in third phase clinical trials and found to be safe and efficacious. Since Dr. Cohen had overcome many scientific hurdles to create the first efficacious malaria vaccine, he could look back on the history of the vaccine and give a teleological narrative of success and completion. Thus, his narrative was fairly smooth, with few detours in the story to discuss the contingencies, missteps and dead ends that are normal parts of scientific discovery, making the development of RTS,S appear like an inevitable process.

I began by asking Dr. Cohen about his desire to work on RTS,S and he explained that his upbringing played a role in his work on a malaria vaccine:

I was born in ... Egypt and I grew up there.... I have experienced first-hand a life in a developing country. I was part of a privileged class of people but I grew up seeing with my own eyes what it is to live in a very poor country. I think that has had some impact on my desire to do science.... and when it came to choose a job, working on something that could have a benefit for people living in very poor countries [was important].

Dr. Cohen continued, entwining the story of RTS,S with his own life story. In the early 1980s, he obtained his PhD in molecular biology at New York University (NYU). In 1984, Dr. Cohen joined the pharmaceutical company SmithKline and French<sup>13</sup>. He was hired to work on a variety of vaccines as a microbiologist but in April 1987 he was asked to head the Malaria Vaccine Project team. Dr. Cohen accepted this offer and began work on what would later be called the RTS,S malaria vaccine.

Dr. Cohen explained that the building blocks of the RTS,S vaccine began with the identification of the 'circumsporozoite protein', or CSP, in the laboratory of Drs. Ruth and Victor Nussenzweig at NYU. Funding for this study stemmed from the US Department of Defense. Speaking about this discovery, Dr. Cohen said that the Nussenzweigs had "discovered, identified, this antigen [CSP] in the late 50's, early 60's. They studied it and made the hypothesis that that was a potential component for a vaccine." In 1967, Dr. Ruth Nussenzweigs et al. reported success in immunizing mice against malaria using weakened sporozoites that had been altered so they became less virulent but were still alive (Badgett et al. 2002; Hoffman et al. 2002; Franke-Fayard et al. 2010; Sherman 2009). This finding was the impetus for similar studies in humans. During the 1970s, several studies demonstrated that humans could be immunized against malaria if infected with P. exposed to X-rays and been weakened. This demonstrated that it was possible to vaccinate people and provide protection against malaria invading the liver (Hoffman et al. 2002; Vekemans et al. 2009).

From 1989 to 1999, researchers explored this process, finding through human studies that exposure to malaria from irradiated mosquitoes led to an immune response (Hoffman et al. 2002). These studies gave scientists an idea for formulating vaccines that targeted the 'pre-erythrocytic stage', which as described above is the phase of malaria infection that takes place before and after the malaria parasite enters the liver and before malaria infection leads to symptoms (Cohen et

<sup>&</sup>lt;sup>13</sup> Over the years there have been many mergers to create GSK and the name has changed several times. When discussing GSK before 1999, one is referring to the legacy companies of GSK (J. Cohen, personal communication).

al. 2010; Girard et al. 2007; Casares, Brumeanu and Richie 2010; Hoffman et al. 2002).

It was impractical to immunize large numbers of people with an irradiated sporozoite vaccine because the sporozoites would need to be delivered via a mosquito or an intravenous injection. Instead, researchers focused on understanding the underlying reasons for this protective immunity (Hoffman et al. 2002). The US National Institutes of Health (NIH), USAID and the WHO provided funding for this next stage of research. Scientists found that rodents vaccinated with irradiated sporozoites developed antibodies that neutralized malaria infection. The immune system was able to identify and abolish the sporozoites infecting the body by identifying a protein on the surface of the sporozoite. This protein was later identified as the 'circumsporozoite protein', or CSP, a protein that covers the surface of the malaria parasite sporozoites and is responsible for latching onto humans when infecting them. Once the body had identified this protein from sterile parasites, it could mount a defence and later protect the body from fully pathological malaria parasites (Cohen et al. 2010). With this understanding of infection and immunity, there were hopes that a vaccine would be found very quickly (Sherman 2009).

Once the CSP had been discovered, researchers at NYU applied for a patent to clone the CSP in 1981. Although NYU sought to sell the patent rights to a genetic engineering company to produce CSP, public funders of the research blocked this. The WHO objected to this sale because they wanted to maintain "public access" (Sherman 2009: 254) and USAID technically held the patent for the research it supported at NYU. By 1983, researchers at NYU were able to produce CSP through cloning themselves. However, despite previous attempts to block its sale, in 1989 NYU licenced the patent for the CSP to GSK in a non-exclusive and royalty free deal (Sherman 2009).

At the same time, researchers at The Walter Reed Army Institute of Research (WRAIR) were experimenting with the CSP. In 1984, WRAIR genetically sequenced and cloned the CSP, allowing for the development of a malaria vaccine (Sherman 2009). Administered by the US Department of Defense, WRAIR is the largest biomedical research facility in the US and is situated in Silver Springs, Maryland. WRAIR conducts biomedical research that responds to the needs of the US Department of Defense and the US Army, including studies on infectious diseases and the development of drugs and vaccines for malaria, dengue and

HIV/AIDS (WRAIR 2017). Early in 1984, WRAIR and GSK entered into a collaborative research and development agreement to create a malaria vaccine. As Dr. Cohen said, "the idea was to develop a vaccine that could serve … where malaria was endemic, but possibly a vaccine for travellers. Included in the definition of travellers is, of course, military; they tend to travel."

The WRAIR had investigated malaria for many years, contributing significantly to the foundational research that underlies RTS,S, and by the late 1980s, GSK held the patent for the CSP and the technology to produce CSP in large quantities (Sherman 2009; WRAIR 2011). Together, scientists at both institutes developed nearly a dozen different vaccines that were tested pre-clinically and produced six different vaccines that were tested in laboratories at WRAIR in the US and in malaria endemic regions in Africa. At the same time, a team led by scientists at NYU were developing and testing a malaria vaccine variation (Cohen et al. 2010; WRAIR 2011). Each of the vaccines were tested in 'challenge models' in laboratories in the US. Dr. Cohen provided an explanation of a human challenge model:

[T]he volunteers in a study are immunized with the vaccine and then, in the confines of the laboratory, with proper follow up, you challenge the volunteers by having them bit with infectious mosquitoes in a container. Follow up is done to find out if the vaccinated volunteers have contracted malaria and if the vaccine works. The volunteers who were not protected by the vaccine were treated for malaria as soon as parasites were found. The challenge model is useful to allow people to find if a vaccine works or not.

However, a majority of the vaccine candidates performed poorly and were not developed further.

One vaccine candidate was field tested in a phase 2b trial amongst Thai and Kenyan volunteers at overseas laboratories owned by the WRAIR. However, this vaccine candidate was found inefficacious (Cohen et al. 2010; Regules, Cummings and Ockenhouse 2011; Kester et al. 2000; WRAIR 2011). Where once there was great optimism that a vaccine would be found, by the late 1980s and early 1990s, there was widespread disappointment and skepticism that a malaria vaccine would be developed (Cohen et al. 2010).

In 1987, the results from testing vaccine candidates were not encouraging. The research by Hoffman et al. (2002), demonstrated that humans could be protected against malaria infection with CSP-based vaccines but it was unclear how to employ this finding to create a vaccine. The malaria vaccine program at GSK had moved its laboratories in Philadelphia to Rixensart, Belgium. It was then that Dr. Cohen was asked to take charge of the Malaria Vaccine Team at GSK and see if he could devise some new ideas for developing and improving the vaccine (Sherman 2009).

GSK had been in the process of completing a hepatitis B vaccine in 1984 when Dr. Cohen began working at GSK and the first genetically engineered vaccine against hepatitis B was registered in Europe in 1986, named Engerix-B™ (Cohen et al. 2011). Dr. Cohen said, "I was very much impressed with the ... kind of molecular biology, that these scientists in industry were doing." As he headed the Malaria Vaccine Team, his team of scientists devised a new molecule to help increase the performance of the vaccine, employing similar genetic engineering techniques as used to develop the hepatitis B vaccine. This newly formulated malaria vaccine was created by partitioning one gene from the hepatitis B virus and combining that with the CSP discovered by the Nussenzweigs at NYU. The combination of virus and parasite genes assembled into virus-like particles and were transferred to yeast cells using molecular biology techniques. These genetically modifying yeast cells then produced large quantities of these virus-like particles. Dr. Cohen described this process: "These proteins inside the yeast cells were assembled together into a little ball of sorts, a few nano meters in diameter, that looked like the virus but with no pathological material ... in it whatsoever... that would be a protection against ... malaria,". "This hybrid formed particles looked like virus particles.... The immune system thinks it's a virus and responds better."

This was not enough for an efficacious malaria vaccine and in 1989, scientists began developing an adjuvant system to boost the immune response to RTS,S (Casares et al. 2010; Cohen et al. 2010). As discussed above, an adjuvant is a substance added to vaccines and other medicines to boost the immune response (NIH 2008; Brownstein 2009). Adjuvant systems (AS) were developed, derived from the bark of a plant and two were found to be efficacious: AS01 and AS02 (Casares et al. 2010; Cohen et al. 2010). Dr. Cohen explained this development:

While the trials were running, we were working on improving adjuvants and we were doing trials ... on mice and ... rhesus monkeys. But we also were doing trials on humans ... to see if any new adjuvants that we were developing would be better. Indeed, one adjuvant...called AS01, was ... better

than AS02.... [W]e switched to AS01 and that's the one we did the phase 3 [trial] with and ... that's the one that will go into the final vaccine.

Dr. Cohen summed up the development of RTS,S vaccine and the adjuvant, AS01: "We took this protein that people had been working with for many, many years, the CSP, and failing. We hooked [the CSP] up to the hepatitis B protein to produce particles. We formulated [the vaccine] with adjuvants and that form of the RTS,S vaccine finally gave us some positive results." This new and improved vaccine took nine years to develop.

The vaccine needed to be tested to see if it was an improvement on the last formula and in 1996, GSK with the WRAIR worked together to test the vaccine on human volunteers at WRAIR in the US (Cohen et al. 2010; PATH-MVI 2016). The outcome was very positive, as Dr. Cohen explained:

> We were fortunate that the vaccine actually worked and worked in the first study very well. Out of the study volunteers that had been immunized with the malaria vaccine and challenged with the bite of infected mosquitoes, six out of seven were completely protected. After that we tested in many different applications ... [through] the challenge model and the efficacy was more in the range of 50%.

These studies were carried out on a very small adult population, volunteers who had never experienced malaria or been to malaria endemic regions. That was the first strong indication that the candidate vaccine could protect against malaria.

The outcomes of the challenge model tests were encouraging but the efficacy rates called into question the ability for RTS,S to protect travellers and military personnel. I spoke about this issue with Michael, a representative of the Malaria Vaccine Initiative (MVI), via internet video call in 2015. He stated,

[RTS,S] had been worked on by GSK and Walter Reed back in the '80s [and] it showed some promise but not promise for the clientele they were looking for.... Given that Walter Reed was involved, I'm not going out on a limb to say that they were looking for a malaria vaccine for the military. But the efficacy they were getting really wasn't showing that it was going to be what the military would need.... And as you know, children in Africa with falciparum malaria, that's the biggest killer and that's the ones most affected by the malaria disease. So, the impetus was to try RTS,S with pediatric populations. However, developing a vaccine for African children was not always the main goal of GSK and WRAIR. With efficacy levels of RTS,S lower than hoped, the vaccine became targeted towards young children only after disappointing results. Dr. Cohen explained the need to develop a more efficacious malaria vaccine for travellers and military personnel:

> [People] are working on vaccines that can be used by ... military personnel, or by travelers, various groups of travelers. That is a completely different project that requires that a vaccine be extremely highly efficacious to compete with what travelers or military personnel can do today to protect themselves against malaria, which is to take preventative drugs, pills.... [T]hese are efficacious at near to a 100%. Making a vaccine that can reach very high efficacy, and even a vaccine that can be easily taken by a traveler which means that it requires one, or maybe a maximum of two injections—we are really very far from anything like this today.

Although less efficacious than hoped, the RTS,S malaria vaccine protects against the species, *Plasmodium falciparum* by triggering the immune system when the sporozoites of the *P. falciparum* malaria parasite enter the bloodstream after the bite from an infected mosquito and/or when the parasite infects the liver. The vaccine prevents the parasite from infecting, coming to maturity and multiplying in the liver and from later re-entering the bloodstream and infecting red blood cells, the point at which the affected person would begin showing symptoms of malaria infection. Dr. Ripley Ballou at the WRAIR and Dr. Joe Cohen at GSK were named co-inventors of the vaccine. As the history of the RTS,S malaria vaccine demonstrates, the science behind the vaccine was informed by previous technological and scientific breakthroughs and a growing understanding of the malaria parasite and human immunology. Also, at each stage of development of RTS,S, the body of knowledge about biology grew, as did the tools available to researchers, allowing for refinements of the vaccine (Cohen et al. 2010; Vekemans et al. 2009; Sherman 2009; PATH-MVI 2016). Additionally, institutional arrangements shifted that saw the sale of publicly funded research to a private company and the formation of a partnership between the WRAIR and GSK to fund and support research activities.

Once the formulation of the vaccine was tested and confirmed to be efficacious in small-scale studies in laboratories, researchers wanted to see if RTS,S prevented malaria under more realistic conditions in the field, in the places

where the vaccine would potentially be used. Below, I discuss the vaccine clinical trials that were carried out between 1998 and 2014 and how they were increasingly scaled up from small trials involving a few adults to involve thousands of young children (PATH-MVI 2016).

#### Testing RTS,S: Phase 1 and 2 RTS,S Vaccine Clinical Trials

In 1998, GSK and WRAIR began collaboration with the UK Medical Research Council (MRC) and a program was set up to test the vaccine in the MRC field station in The Gambia in a phase 1 trial. Adult men were vaccinated and the safety and immune response to the vaccine was demonstrated under natural exposure to the malaria parasite. Subsequent trials—phase 2a and 2b—were carried out in Gambian adult men, providing proof that RTS,S was efficacious under natural malaria exposure (Cohen et al. 2010). "Lo and behold, the vaccine was indeed offering partial efficacy against naturally challenged malaria in the field on African challenged volunteers," Dr. Cohen explained. At the conclusion of the trial, there was 47% efficacy rate (Cohen et al. 2011; Girard et al. 2006). Over the next five years, this population was monitored to determine long-term safety and efficacy of the vaccine (Cohen et al. 2010).

The outcome of the vaccine trial at the MRC research centre in The Gambia encouraged GSK to continue with the testing of RTS,S amongst a younger population in Africa. Dr. Cohen said, "In order to test the vaccine targeting infants in Africa, there was no other way of testing it other than actually in the target population, and in the geographic region where that target population resided. So, just in terms of regulatory issues, if we expect to have the vaccine licensed and registered and implemented, we had to do this testing in Africa." However, this undertaking was anticipated to be quite costly. Although GSK and the WRAIR were able to fund vaccine development up until this point, they were unable to provide funding for further phase 2 trials and a large-scale phase 3 trial. Many vaccines that are unlikely to be money-makers tend to have trouble passing from development and testing in laboratories to being tested in the field. This is often due to a lack of funds and support from pharmaceutical companies that anticipate little return on their investment into vaccines for diseases that predominantly afflict the poor (Widdus 2005). Thus, to overcome this challenge, GSK sought outside funding.

Reflecting on this period of time, Dr. Cohen said,

We developers were aware that this would be a tremendously large endeavour, from a scientific point of view and from an organization point of view, and from a cost point of view. We knew how much it cost, on average, to develop a vaccine and this was a rather particular vaccine targeting a rather vulnerable population. Not only vulnerable because they carried the burden of malaria but vulnerable in a more general sense. These were infants, children, in very poor countries. That added another aspect to their vulnerability that needed to be taken into consideration. So, at the end of the 90s and beginning of the 2000s ...we knew it was going to be a complicated and costly project. Because the vaccine was targeting a very poor population, there would be a very low return. And so, we had to develop a new business model to try to address the specific difficulties or hurdles for the development of the vaccine. At the same time, the Gates Foundation was created [in] 1998. And by 1999, the Gates Foundation had itself founded and funded a new organization, the Malaria Vaccine Initiative [MVI].... Its primary goal was to accelerate development of vaccines against malaria.... Very quickly we went to see them with the data we had [from] small trials in African adults in '97. '98. We went to see them to discuss the potential for an agreement. Perhaps at that time these things were not quite known as public-private partnerships but essentially that was what it was.... We had discussions with the Malaria Vaccine Initiative and the Gates Foundation and in January 2001, we entered into a partnership agreement ... whereby GSK and MVI would partner and share the risks and the costs of developing this malaria vaccine. This partnership has been there over the years as the project progressed and is still honoured today.

Acknowledging that a malaria vaccine for African children would not likely lead to great profits for GSK and knowing that a large-scale clinical trial of RTS,S would be a great undertaking, partnering with a non-profit organization was key for RTS,S to progress in its development. GSK teamed up with the Malaria Vaccine Initiative (MVI), which was created as a branch of the US-based non-profit organization, Program for Appropriate Technology in Health (PATH), based in Seattle. PATH and MVI share financial and administrative systems. MVI was set up in Bethesda, Maryland in 1999 and with a large grant from the Gates Foundation for US\$50 million, helped carry out the phase 2 and 3 clinical trials for RTS,S (MVI representative, personal communication; Sherman 2009; Chataway et al. 2010). Michael explained the involvement of the Bill and Melinda Gates Foundation and their large financial investment: "They saw the value of a malaria vaccine; they see the value in vaccines generally. The Foundation is very hot on this. Melinda Gates is very hot on malaria; she's doing something about it because it's such a killer."

MVI's mission is "to accelerate the development of malaria vaccines and ensure their availability and accessibility in the developing world." (Chataway et al. 2010: 1285) There are three aspects to their mission: 1) product development; (2) access to products; and (3) working with countries where malaria is endemic in order to ensure that those countries have leadership and ownership of vaccine use. Chataway et al. (2010) describe MVI is an integrator, bringing together a mix of stakeholders and organizations in order to ensure that the vaccine candidate was successfully taken from 'bench to bedside' (Chataway et al. 2010: 1285). MVI has a portfolio of around 20 malaria vaccines, each at different stages of development (Sherman 2009; WHO 2016a).

Michael remarked about the partnership between GSK and MVI:

There was probably too much risk for GSK to undertake these trials all on their own. A lot of money, a lot of capacity building required for these large-scale trials in Africa so they needed a partner that was willing to off-set some of that risk if things didn't work out.

The contract between GSK and MVI took a year to negotiate and clearly stipulated in a charter under the partnership agreement what the roles, responsibilities and key deliverables were for each party. GSK served as the regulatory sponsors of the trials and MVI coordinated trial activities and funded operating expenses, including resources, equipment and staff training for the clinical trials. Dr. Cohen reflected on the partnership between GSK and MVI. "[I]it's a complex partnership.... [T]here is an agreement that isn't just one page that says, "We'll work together" and that's it. What are the deliverables, with who will do what, with a charter under the agreement."

With this partnership in place, RTS,S vaccine clinical trials were conducted across Africa. As Dr. Cohen explained, "We began progressing very carefully to the younger populations and ultimately to the infants." A pediatric version of RTS,S was developed and around 3,000 children ranging in age from 6 weeks to 11 years old were vaccinated from 2004 to 2009 in The Gambia and Mozambique. Through these trials, the vaccine was demonstrated to be safe for children. In 2004, a trial was carried out in Mozambique to demonstrate the efficacy of RTS,S in the pediatric population in a large, double-blinded study amongst 2,022 children aged one to four years old. The efficacy was around 35% against first clinical episode of malaria and

49% efficacious against severe malaria over an 18-month period. The benefits lasted over 45 months and the vaccine was found to be safe (Cohen et al. 2010).

Beginning in 2007, the next phase of testing was conducted in Mozambique amongst younger children who were receiving vaccines as part of the Extended Program of Immunization (EPI). This trial assessed the efficacy of RTS,S in children aged 8, 12 and 16 weeks when administered with EPI vaccines, including the tetanus, diphtheria and pertussis vaccines (Cohen et al. 2010). Many children around the world receive their childhood vaccines through this program and being able to administer RTS,S through the same program would lower administration costs (WHO 2017a; RTS,S Vaccine Trial Administrator 2013, personal communication). As Dr. Cohen explained, RTS,S "is meant to be implemented from existing channels of implementation of vaccinations for kids in Africa. This is the so called Extended Program of Immunization … through which kids in Africa receive their standard courses of vaccinations today with existing registered and recommended vaccines. This is an existing system that works extremely well [and] covers … about 75% of the kids in Africa." During this trial, RTS,S was found to be 66% efficacious.

From 2006 and 2008, a subsequent trial was carried out in Korogwe, Tanzania<sup>14,15</sup> and Kilifi, Kenya. In Korogwe District, children from 17 villages were enrolled in the trial, which operated out of the pediatric ward of Korogwe District Hospital, with three trial dispensaries<sup>16</sup> used as vaccination sites. The vaccine was similarly efficacious as in previous trials (Cohen et al. 2010; Olotu et al. 2011; Liheluka et al. 2013). Speaking to Sharon, a representative of MVI, via internet video call in 2015, she explained, the phase 2 trial in Mozambique was a "preparatory study,… kind of like a shake down." It was a chance to enhance referral systems and pediatric care services in the area in order to ensure that when

<sup>16</sup> Informants referred to health care dispensaries built for the RTS,S trial as "satellite dispensaries" because they were located in villages around the Korogwe Research Centre.

<sup>&</sup>lt;sup>14</sup> In 2005, in preparation for the phase 2 RTS,S vaccine trial, a demographic surveillance system was set up in 14 villages in Korogwe District (Nyika et al. 2010).

<sup>&</sup>lt;sup>15</sup> Before the RTS,S trial began, ethical clearance was obtained from the relevant medical research organizations both internationally and in Tanzania. MVI employed people who had decades of experience conducting clinical trials in Africa and had expertise in navigating this part of the research. Once a site at the Korogwe District Hospital was identified to support the trial, meetings were held with administrators at the Korogwe District Hospital and district medical officers who oversaw the health care system in the area. Once these people approved of the RTS,S trial, trial staff could begin their work of community engagement and recruiting research participants (MVI Representative 2015, personal communication).

participants fell ill, the necessary steps would be taken for them to receive care and have samples collected for analysis. These positive outcomes and improvements in care led researchers to progress to a large-scale phase 3 study for infants and young children.

#### Phase 3 RTS, S Vaccine Clinical Trial

From 2009 to 2014, a phase 3, randomized control trial of RTS, S, was carried out in seven African countries. The trial involved over 15,000 children in two age groups. The trial participants were divided into three groups: one group was administered the vaccine in three doses, along with an alternate vaccine as a booster shot; a second group receiving four shots of RTS,S (which included an active booster shot); and a third group received four shots of an alternate vaccine (a rabies vaccine was given to the older group of trial participants and a meningococcal vaccine for the younger group). There were three vaccines provided to each participant, once a month for three months, with a fourth shot provided to a third of participants after a year as a booster. Researchers wanted to know if RTS,S could prevent malaria and if an additional dose a year after the first RTS,S dose boosted the performance of the vaccine. Participants were randomly assigned to one of the three groups and since the trial was double blinded, neither the researchers or participants knew which participant received RTS,S or an alternate vaccine. MVI provided funding for the trial, which stemmed from the Bill and Melinda Gates Foundation, with a bit of funding from USAID and ExxonMobil for communication training for trial staff and the conduct of ancillary studies on malaria transmission (RTS,S Clinical Trials Partnership 2015; MVI Representative 2015, personal communication).

GSK and MVI remained partners while entering into multiple collaborations with the African research institutions conducting the RTS,S clinical trial. For each of the 11 trials sites across Africa, a publicly or privately funded African research institute conducting the trial and many of the trial sites formed affiliations with an academic institution in Europe or the United States. Dr. Cohen described the collaborations: "In total there are more than two dozen collaborations between ...

However, in order to simplify terminology, I have used the term "trial dispensary" to refer to these dispensaries throughout the thesis.

African and European or American institutes." Speaking to Tom, a British malaria research and co-Principal Investigator (PI) of a West African RTS,S trial site, he explained the role of northern academic institutions in the trial:

Many of the sites have Northern partners that they've worked with and ... some small amounts of money came from [them]. [Northern partners] helped, especially in the beginning when [people were] getting the trial off the ground.... They are really good, giving help in that way. In the beginning, [trial sites] really needed help with how to actually run a vaccine trial and [Northern partners] are there to offer support.

In Korogwe, Tanzania, the RTS,S trial was supported by the publicly funded Tanzanian National Institutes for Medical Research (NIMR), but was solely funded by MVI and had no affiliation to a Northern academic centre. Other trial sites had different arrangements. For example, the other vaccine trial in Tanzania was conducted in Bagamoyo, just north of Dar es Salaam. There, the trial was carried out by the Ifakara Health Institute, a non-profit research organization largely funded through grants from world governments, with an affiliation with the Swiss Tropical and Public Health Institute (IHI 2016; Tanner 2017).

Although most African trial sites developed partnerships with Northern institutions, the partnership between GSK and MVI required new governance structures as the roles of each organization centred on the phase 3 trial. Sharon spoke about this shift:

MVI played a role ... in partnership with GSK because they are ... the regulatory sponsors. So, one of the roles that MVI had was that we funded all the [trial] sites. In other words, we paid for their operating expenses, for their budget. So MVI staff were intricately involved in working with the sites for resources, budgets, equipment, training. Then, on an ongoing basis, MVI staff were the ones that coordinated what is called the CTPC, the Clinical Trials Partnership Committee. That was the next tier of the governance structure of a network-wide way to communicate and coordinate among all of the sites, creating that harmonized 11-centred network.

Speaking to Dr. Cohen about how the partnership operated, he said,

We have a steering committee that represents GSK and the Malaria Vaccine Initiative that actually steers ... the overall strategy of the project and manages the overall project. With the steering committee, [it] has 14 members for GSK and MVI but also has ... an observer from the Gates Foundation

and there are observers from the African collaborators. And in addition to this particular steering committee between MVI and GSK, there is a committee that brings together *all* of the ... collaborating institute in Africa, in the US and Europe and it's called the CTPC, Clinical Trial Partnership Committee. This has representatives of each of the collaborating sites and each of the collaborating institutions come together in this committee. They actually deal specifically [with] work on the clinical trials,... they have the final say on the way the results of the trial are ... drafted and published, et cetera.

I spoke to Isabelle, a RTS,S vaccine scientist at GSK via telephone in early 2014.

She described the need for a partnership.

This is clearly something that the company would not have been able to develop on its own. On the other hand, the other partners would have not been able to do it on their own because we have the clinical infrastructure [and] know-how to use the existing infrastructure in Africa. We have the capacity to manufacture, et cetera. But on the other hand, we need the support, not only in term of risk-sharing and cost-sharing, but also in terms of expertise. We really need the expertise and the views of the people, like the Gates Foundation, like PATH-MVI. But more importantly from the people on the ground [in Africa]. It is really critical that each of us brings in expertise.... It's really trying to put ... all the minds together and ... [have] each other's expertise and knowledge.

Sharon reflected on the social relationships formed through the RTS,S vaccine trial: "when the trial was going on, at any given point there were 1000 people dedicated to the trial. It's an incredible effort.... We had *a lot* of dedicated people making this happen." Dr. Cohen also spoke about how activities were coordinated between the many people and organizations involved:

It's not a simple matter, and it is done by ... committees and ... a lot of emphasis on transparency and making sure that everyone is involved and aware of what is happening. Many face-to-face meetings. That's how hundreds of people have been working on that.... It was done successfully I think, very much so.

At the end of the trial, researchers found that the efficacy of RTS,S waned over time. Three shots of RTS,S led to a 28% efficacy rate but three shots of the vaccine along with a booster shot 20 months after initial vaccination led to a 36% efficacy rate for the older group and 26% for the younger group after four years of

follow up. After seven years, that efficacy of four shots waned to 4.4% (Olotu et al. 2016; RTS,S Clinical Trials Partnership 2015; Moorthy and Okwo-Bele 2015).

Researchers now know why results of the vaccine trial are lower than expected. As discussed, vaccine researchers used a protein found on the surface of malaria parasite, the CSP, to manufacture RTS,S. However, different malaria parasites have slight variations in their proteins, something that researchers 30 years ago were unable to detect with the tools available at the time. Using new DNA sequencing tools, researchers analyzed the parasites that infected 5,000 of the children involved in the phase 3 trials. Fewer than 10% of the parasites found in these participants had a matching protein to the one used in the RTS,S vaccine. RTS,S was partially efficacious to malaria parasites with mismatching proteins but worked best when the proteins were an exact copy. Researchers are now looking into including a variety of proteins in newer malaria vaccines (Neafsy et al. 2015; Maxmen 2015).

Although these outcomes might be considered disappointing, Dr. Cohen did not feel this way. Reflecting on the phase 3 RTS,S vaccine trials, he said,

[The trials] are recognized as high quality trials, so that is fantastic given where we started. Not easy. And as far as the results, we are very happy.... The efficacy ... is partial ... but that was something we knew almost from day one. So, the trials we performed at Walter Reed suggested an efficacy of about 50% overall. When we went into the field that is what we saw.... But for us ... it is still an excellent result because ... the public health impact of that level of efficacy, and the human impact of that level of efficacy, is enormous. Because the disease has such a high burden.... It sends ... millions to the hospital each year.... If you can have an impact of 50 or even 30% on these numbers, you have a tremendous public health impact, of course. So, we are very happy with the results.

Several informants emphasized that RTS,S is no magic bullet and if deployed it will be added to existing prevention methods, such as insecticide-treated bed nets. As Dr. Cohen said:

> The malaria vaccine is an additional tool, completely different in its mode of action, completely different in its implementation.... We are simply saying this is an additional weapon in the arsenal to fight malaria and it has its role and its place because it is actually very different from the other preventative measures.... [T]his is not the silver bullet that will resolve ... the malaria problem, it's not going to eradicate or eliminate malaria in Africa. But it will save lives. It will

prevent children from being sick and having to go to hospital and having ... severe malaria. It will prevent millions of ... uncomplicated cases of malaria. It has an important role to play from that point of view.

Joseph, a RTS,S trial administrator in Korogwe, echoed this: "in my view and the view of other scientists that I know, [RTS,S is] to be used in combination with other existing malaria interventions." This may put strain on already underfunded malaria control efforts in Tanzania but some people I spoke to viewed RTS,S as a stepping stone towards more effective malaria vaccines. As Tom said,

The next step is to come up with a better vaccine. There are 20 other vaccines at various stages.... [T]he malaria vaccine will be licensed and used in some places but that will encourage the development of better vaccines.... I don't think we'll get a vaccine that will get 100% protection.... It will be a gradual process. You will probably get combinations of vaccine that get up to 60% or they will develop something else that gets it better than that but it will be a gradual process.

With the data collected from the large-scale clinical trial, researchers and policy makers could see that RTS,S was able to prevent malaria in about a third of cases. This could pave the way for RTS,S to be eventually provided to children in Sub-Saharan Africa, as well as the development of other malaria vaccines. I now turn to a discussion about the steps towards widespread provision of RTS,S.

### Steps Toward Future Provision of RTS,S

In July 2014, GSK submitted the results of the phase 3 trial to the European Medicines Agency (EMA) under article 58. Article 58, which devised by the EMA and the WHO, states that the EMA will review and offer an opinion on new drugs that are developed in Europe but are not destined for the European market. This process did not lead to drug licensure but the EMA gave a scientific opinion on the safety and use of RTS,S. In July 2015, the EMA determined that RTS,S was efficacious and safe for use amongst the younger and older age groups of children included in the third phase of the trial (J. Cohen 2013, personal communication; PATH-MVI 2016; Greenwood and Doumbo 2016).

After this recommendation, two WHO advisory groups—the Malaria Policy Advisory Committee and the Strategic Advisory Group of Experts on Immunizationreviewed the file on RTS,S. These committees provided a recommendation about how the vaccine should be used in Africa and developed guidelines for its provision. In the phase 3 trial, vaccine efficacy was low among the younger group of children aged 6 to 12 weeks. Due to this outcome, the WHO recommended that RTS,S only be used amongst the older age group, the 5- to 17-month old children (Greenwood and Doumbo 2016; WHO 2016; Moorthy and Okwo-Bele 2015).

The WHO advisory groups also recommended large-scale pilot studies be undertaken before widespread use of RTS,S. Three pilot studies will commence in three different African countries, beginning in 2018. The pilot studies will assess whether existing immunization programs are able to deliver four doses of RTS,S, whether the vaccine is as safe as demonstrated in the phase 3 trial, and whether the vaccine is effective in preventing death in real-life settings. The WHO is yet to decide which countries will undertake the pilot studies but priority will be given to countries that have participated in the phase 3 trial. Additionally, each setting for the pilot studies will have a high burden of malaria and functioning immunization and malaria programs. The pilot studies will be amongst 5- to 9-month-old children. Funding for these pilot studies will come from the Global Fund to Fight AIDS, Tuberculosis and Malaria, GAVI—the Global Alliance for Vaccines, and UNITAID<sup>17</sup>. So far, US\$49.2 million has been pledged for a three-year pilot program (PATH-MVI 2016; Greenwood and Doumbo 2016; WHO 2016b; WHO 2017b).

After the pilot studies, policy makers in individual countries will decide about providing RTS,S and the extent of that provision. Since countries where RTS,S will be deployed tend to be impoverished, they will have to seek out donor funding for the vaccines to be purchased and deployed. As Dr. Cohen explained, "the people that are the final target of the vaccine clearly are not able to pay for the vaccine and *will* not pay for the vaccine.... These vaccines are being funded by donors. In some cases, the countries contribute a certain amount, usually a small amount, and in many cases, the purchasers of the vaccine are in fact run through [GAVI]." As for the cost of RTS,S, Dr. Cohen explained that GSK will not make a profit from the sale of RTS,S. GSK aims to set the price at US\$5 per shot, the same price as an insecticide-treated bed net. This cost will cover vaccine manufacturing costs along

<sup>&</sup>lt;sup>17</sup> UNITAID was founded in 2006 by the WHO to fund the last stages of development and research for new drugs, including the production of data to support guidelines for use. Located in Geneva, Switzerland, UNITAID is funded by France, Norway, Chile, the Bill and Melinda Gates

with an additional 5% that GSK will invest in research about malaria and neglected tropical diseases (MVI-GSK 2015).

Penny et al. (2016) conducted a cost-effectiveness analysis of RTS,S vaccinations in a range of different settings in Africa. With a 75% coverage rate with four doses of the vaccine, RTS,S would be cost-effective in a variety of places, as long as the vaccine cost between US\$2 and \$10 a dose. The researchers predicted that the introduction of the vaccine could make a substantial and positive impact on public health in many places in Africa. Providing four doses of the vaccine could avert "484 ... deaths ... per 100,000 vaccinated children ... This finding translates to roughly one malaria death prevented for every 200 children fully vaccinated" (373). This modelling will help shape policy recommendations for where and how RTS,S will be provided in Africa, as well as donor funding for the vaccine (Penny et al. 2016; Greenwood and Doumbo 2016). I now turn to a discussion about the partnerships established during the phase 3 RTS,S vaccine trials in Africa.

#### The RTS,S Vaccine Partnerships

Throughout the development of the RTS,S vaccine, a combination of new scientific tools, funding mechanisms and global health partnerships made the vaccine possible. RTS,S started as a molecule in a university laboratory and then became the patented property of GSK. Different institutions and organizations were involved in laboratory research or clinical trials as the vaccine progressed and went from potentially having military applications to being formulated for pediatric populations in Africa. The earlier partnerships were formed between Northern companies and institutions; each had ample resources, making relations more equal. As well, these actors were engaged in partnership over years and decades, allowing people time to build relationships. Later in the development of RTS,S, partnerships were forged between GSK, MVI and African research institutions. These later-stage partnerships involved larger differences in wealth and resources and operated for only a few years, which likely made it difficult

Foundation, UNICEF, the Global Fund and other countries and global health donors (UNITAID 2017).

for people to develop strong relationships of trust and mutuality. Below, I explore people's thoughts on these later partnerships.

Reflected on the establishment of partnerships between dozens of organizations in Africa, Europe and the US, several informants portrayed the partnerships positively, describing them as successful. Dr. Cohen, discussing the partnership between GSK and MVI, said: "It's a partnership that … we have been completely transparent …, visa-vis, the partners with each other … and that has been really critical in our capacity to get this vaccine to a stage where it is today." Michael said, "if you see in the latest publication in *The Lancet*, the sites and partnerships succeeded." From Michael's perspective, the RTS,S trial also fostered relationships between trial sites in Africa:

The things that proved to be essential is that in some of the countries there was more than one trial site.... [S]ome of the countries it was the RTS,S vaccine partnership that got those research centres talking to each other. Even though they were in the same countries, they were kind of in their own silos in some cases and this trial ... actually got these guys talking together, to their mutual benefit, outside of RTS,S.

Sharon also spoke highly of the partnerships: "We would set goals and a lot of time we would make them and if we didn't and ... there was some unanticipated roadblock or challenge or something we didn't think of, the teams worked together to solve them.... I do believe that ultimately ... [the] PIs felt respected and that they had a place at the table. That they were part of the decision-making and it wasn't just top-down."

For the most part, representatives of GSK and MVI spoke about the positive aspects of partnership. At the time of the interviews, the RTS,S partnerships had come to an end. Informants were confident that through the partnerships, they had been successful in developing a malaria vaccine, publishing multiple articles in reputable academic journals, building African capacity to conduct biomedical research, and encouraging African research institutions to collaborate. Thus, from their perspectives, these partnerships had been positive and mutually beneficial.

Nevertheless, some informants revealed some of the difficulties that arose during the course of the partnerships. Tom said, "obviously, everyone wants to know whether the vaccine works, that is the primary purpose of the whole thing. But there are lessons to be learned about how partnerships can come together. And not everything has gone perfectly and I think those are important lessons as well." The two representatives of MVI, Sharon and Michael, spoke frankly about some of the difficulties encountered while testing RTS,S. They had first-hand experience of these difficulties since they coordinated the various people and organizations involved in the trial. Sharon recalled technical difficulties, saying, "You should try to organize and convene a teleconference with numerous African sites.... It's actually impossible!" She spoke of generators going down and the internet operating inconsistently, making communication difficult. To help with this situation, MVI had regular visits to trial sites to deal with issues on the ground and there were many face-to-face meetings between partners and trial site representatives. Sharon said, "It took a lot of strategic planning and ... there are a lot of uncertainties. We had this mantra: We are going to plan for success'. Yet, when a challenge came up, we really then had to go into problem solving mode.... Getting the vaccine to the sites and the cold chain, recruiting key personnel.... So many people and so much work went into this." With this, Sharon high-lighted that people cared about making the trial a success and put a lot of labour into establishing and maintaining social relationships, communication channels, and technological systems.

A key component that enabled the trial to operate was coordination, something Michael spoke to:

MVI's role is that we're kind of the honest broker in the partnership. We have the trust and the confidence of the trial sites. We are a not-for-profit and we play a different role than a for-profit company. We are still, to some extent, the backbone of the partnership in terms of having the different parties working together.

From Michael's perspective, MVI was central to the partnership and served as the mediator between GSK and the trial sites in Africa. Michael thought that staff at trial sites placed more trust in the non-profit organization because it was viewed as an altruistic and "honest" enterprise, focused on the alleviation of suffering, and GSK was perceived as being largely motivated by the generation of profit, despite the company demonstrating corporate social responsibility by creating the RTS,S vaccine. This dichotomy between the two organizations meant that each served a different role in the partnership and related differently to staff in Africa.

Sharon spoke to this dichotomy between MVI and GSK when she described the different strategies employed to coordinate and motivate trial staff:

[S]ometimes [the] strategy was very consciously good cop, bad cop (laugh). MVI was usually the good cop. The sites

could come to us and bitch about GSK and we would feel their pain and we would say, 'Yes, they're the big, bad drug company'.... These are not the things that you write in a scientific paper but these are the human aspects of it and the You are managing personalities. management aspects. You know, [the Tanzanian PI in Korogwe] is a personality to manage, and times that by 11. You need to take different approaches to motivate people and to keep them motivated and for them to trust you.... We knew that [trial staff] were padding certain things, like laptops here and there and this and that, but we weren't being draconian with things. We would cut budgets but we understood that they were trying to slide things in.... We are viewed as reasonable people that really knew and understood their challenges and we weren't going to nickel and dime them for stuff. On the other hand, we kind of kept them in line.

Sharon described the role of GSK as being the "bad cop", the organization that was aimed at motivating people to stick to research protocols and be cost efficient. MVI acted as the "good cop", building the trust of trial staff by allowing trial staff to vent to them when frustrations with GSK arose. More than that, MVI was relaxed when funding equipment, allowing trial site staff to add things to budgets and keep laptops, which was a strategy of providing material rewards to motivate trial staff. Yet, MVI also "kept them in line", as Sharon said. This expression demonstrates that she viewed African trial staff in paternalistic ways, assuming that they would be corrupt, steal and misbehave if not monitored. Although representatives of MVI and GSK spoke about the successes of the partnerships, Sharon alluded to the unequal power dynamics and hierarchy at work in the RTS,S partnerships.

Sharon and Michael were frank about issues and challenges that the partnerships and collaborations faced. What Michael and Sharon both expressed also demonstrated the importance of social relationships and the building of trust between actors to carry off a large-scale clinical trial. Mosse (2005), having been involved in carrying out a development project in India, found something similar:

> ... development projects generally are never simply 'implemented' by single-sized actors through formal structures of responsibility; they not only require (and bring into existence) a range of unscripted inter-institutional broker roles, but also need extensive informal networks of support, built personally through relations of trust and maintained through an out-of-sight 'economy of favours and obligations' ... Ultimately, it is not policy consensus, rational planning or bureaucratic procedures that make projects ... run. It is personalities, brokering skills and the channels of influence of individual mediators, buffers and filters. (125)

Projects in either development or global health often operate over vast distances and involve many people who speak different languages and have different aims and expectations. People's personalities, the building of trust, brokering of relationships and the influencing of actors play key roles in the success of such projects. For the RTS,S vaccine partnerships, there were also procedures to solve issues that arose over the course of the trial, which included the use of committees and face-to-face meetings. The committees and other governance structures imposed a hierarchical structure on relationships, making it clear how the different actors and institutions related to each other, as well as clearly outlining expectations for each party. These structures also opened lines of communication, allowing people's issues to be heard and discussed. So, although hierarchy led to clear power differences between people and places, it also organized diverse people and enabled the conduct of a large-scale, multi-sited clinical trial.

The hierarchies and inequalities between Northern and Southern partners were issues that informants reflected on a great deal. Tom downplayed the existence of inequalities, saying,

> Twenty years ago, North-South partnerships were very much dominated by people in the North who wrote the grants, got the money, made the big decisions. They got their African colleagues to sign up and they were very much the junior partner. That of course still happens from time to time but I think that things have changed. For example, with the RTS,S trial,... Ghana gives the money to the London School [of Hygiene and Tropical Medicine, it's Northern partner]. They have the grant so they have control over the money and if they think the London School can offer them something, they bite at it. That is a big change. Now the stronger partner is the African partner.... It hasn't happened in all projects but there is an increasing move [to] giving the money to the African partner. Then that makes them the stronger partner because money has the most influence.... GSK and [MVI] are, to their credit, [allowing] the investigators to make a lot of the decisions.

Simon was the site coordinator and his job involved coordinating the data management, laboratory, clinical and administrative departments at the Korogwe Research Centre. We spoke at length in his dark office one hot afternoon as the air conditioner hummed in the background. Like Tom, Simon understated the inequalities between partners.

Of course, the sites are [very] dependent on the donors and sponsors but ... I can say that the partnership is almost 50-

50 because the site is contributing in getting study participants. You cannot find malaria in Europe so they are dependent on countries that have malaria. They provide funds but the site provides participants. If you have participants but no funds, you can't do a clinical trial and vice versa. You can say that it is almost 50-50, we are depending on each other.

Simon spoke of the dependency that the partners had on each other with the trial sites providing bodies for experimentation and the Northern partners holding the purse strings. However, by describing the partnerships as "almost" equal indicates that Simon thought the balance of power tipped more towards GSK and MVI.

Although Tom and Simon minimized the role of inequality in the relationships between actors and organizations, it was difficult to avoid discussion of this issue. Later in the interview, Simon was more explicit about the differences in wealth between partners:

> [T]hose partnerships, first of all, built capacity for our local people but they also provided funds, they also provided expertise. Without these partnerships ... it was not possible to have conducted a clinical trial here. So, it is very important and we still encourage that kind of partnership.... We have some expertise but we think we need some more time working with them, making sure we are fully independent and can run our own things in our own country. We are still developing, we are still very young. We need to be guided, we need to be shown the way.

This perspective, that Tanzanians are young, in need of guidance and scientific and technological development, is significant. Simon demonstrates that he has internalized feelings of inferiority in relation to those from more 'developed' places, a holdover from colonial times. He employs the notion of immaturity to explain that he views Tanzanians as inferior and in need of help from people from wealthier parts of the world to advance economically and socially and catch up with the 'modern' world. One important way that this advancement can happen, in his viewpoint, is through partnerships with organizations and companies from wealthier and more 'developed' countries. Simon's expression also is strategic and aspirational. While on one hand he is expressing that the RTS,S vaccine partnership facilitated development through the training of locals, he is at the same time downplaying these improvements and expressing the need for continued investment and partnership with organizations from wealthy countries.

Like Simon, other clinical trial staff spoke directly to the issue of inequality. Interviewing Emmanuel, a trial doctor, at the Korogwe Research Centre conference room one afternoon, he said, "We need partnership from outside, we cannot develop that on our own because we have the capacity, we have the knowledge about how to conduct the trials but the problem is the funding, funding for such a big trial. We don't have the money." With this, Emmanuel contradicted what Tom said above and high-lighted that African partners are often at a disadvantage in terms of research funding and thus reliant on outside funders.

Hassan was a fieldworker who had been working for the RTS,S clinical trial since the second phase commenced in 2006. He spoke to the issue of inequality when reflecting on the future of the RTS,S vaccine: "When they administer this vaccine, it will be GSK that benefits the most". Later, I asked Hassan why GSK would be interested in developing a vaccine for a disease that does not affect Europeans and he said, "Because they want to get profits. I know that once this vaccine is authorized to be administered, they will produce more and more vaccines.... [O]ur government might have to buy that vaccine so GlaxoSmithKline will benefit because it will get a lot of money for their vaccine." Quickly, Hassan followed this critique by saying, "We might know this but still this vaccine will help us." Later in the interview, Hassan said: "One day I will be happy I worked on this vaccine."

Hassan openly criticized the motives of GSK, highlighting the potential for GSK to make large profits from RTS,S. He undermined the idea that GSK was acting out of altruism when developing the vaccine, something that most informants avoided discussing. But then he softened his criticism by saying that the RTS,S vaccine would be beneficial to Tanzanians. As well, Hassan thought of his own future, expressing the belief that he would be very happy about his involvement in the vaccine clinical trial. Hassan was clearly grappling with the inequalities and injustices of the RTS,S partnerships and clinical trial. Although he articulated that the vaccine could potentially enrich a wealthy pharmaceutical company, Hassan was expressing that he personally derived meaning from the labour he put into the clinical trial, which fulfilled his desire to save lives. Hassan's involvement in the vaccine trial was his chance to give back, which was a non-commodified form of payment for his labour. For him, this made the inequality less problematic since he felt he was benefiting in non-monetary ways.

Although Hassan and Emmanuel addressed hierarchy and inequality, a few sought to dispel the idea that there was inequality between partners. As Tom said, the money that the African research centres received from MVI and Northern academic institutions helped the research centres assume a level of power in relation to their Northern partners. And Simon described the partnerships as "almost" equal because each partner brought something to the partnership. Nevertheless, the money provided to African research centres was not sufficient to put them on equal footing with GSK and MVI. GSK had immense capital as one of the largest pharmaceutical companies in the world. As well, this company held the patent for RTS,S, and determined how the trial would be conducted. MVI had its own sizeable funding that it channelled to collaborating African institutions, making African collaborators recipients of funding. This position did not confer equality. Nonetheless, some informants sought to undermine the idea that there were inequalities between institutions.

People's level of openness about inequality may relate to their position in the hierarchy of the partnerships. Okwaro and Geissler (2015) reflect on this issue after interviewing African scientists in an East African university. These anthropologists uncovered various opinions about their experiences of collaborative research relationships with Northern institutions. Some scientists downplayed inequality, insisting that partnerships worked well and operated in a smooth manner. Others acknowledged the asymmetrical power dynamics with partnering Northern institutes and described conflicts and frustrations. However, it was difficult for those who insisted that the partnerships worked well to not reference power differences. Okwaro and Geissler thought that the difference in portrayal could relate to the hierarchy between scientists. Senior scientists may have felt the need to pay lip service to partnership and equality since they had to maintain these relationships over time. This portrayal may have also helped these scientists maintain personal integrity and dignity. As well, senior scientists benefited from partnerships through better pay, co-authored publications and presentations at conferences, making them more likely to experience a sense of equality with their Northern partners. But scientists of a lower rank worked as short-term contract employees and did not benefit in the same ways as senior scientists. Thus, they did not have a responsibility or appear to have a desire to portray the research partnerships as frictionless or balanced.

This resonates with my findings. Simon could not help but reference difference in power between partners. But he sought to minimize the hierarchies and this may have been because he was in a management position with long-term employment at the Korogwe Research Centre. Emmanuel and Hassan, on the other hand, were contract employees and had little responsibility in representing the partnerships as equal. Furthermore, they did not benefit from the partnerships over the long-term since their employment ended when the phase 3 clinical trial ended. Thus, their position in the hierarchy may have shaped their reflections on the partnerships and their willingness to take a critical viewpoint.

As for informants at GSK and MVI, they were looking back at the partnerships after they had ended. These people could reflect on the partnerships and expressed feeling good about RTS,S development and building capacity in Africa, which may have made the frictions between people more acceptable. As well, these informants did not have to confront the inequality in the same way as trial staff because they were in a position of power in relation to their Southern partners. It was trial staff who were in a lower position relative to their Northern partners and had to come to terms with this situation.

In this chapter, I laid foundation for subsequent chapters by providing background on the history of malaria vaccines and the RTS,S malaria vaccine development, from its creation in laboratories, to field testing in several vaccine clinical trials in Africa, and evaluation for future use. This history was informed by interviews with Dr. Cohen, who provided a narrative from the perspective of someone who has successfully reached the end of a long research journey. I also explored the social relationships established between different actors and organizations over time, describing how the formation of various partnerships have been integral to the development of RTS,S. Although many of the partnerships throughout the history of RTS,S were established between GSK and wealthy organizations in the North, in later stages of the vaccine development, partnerships were forged with Southern research institutions. Informants at GSK and MVI reflected on these partnerships after the vaccine trial ended and described them as successful. These people could look back on these arrangements and perceive them as beneficial for everyone involved because the partnerships built capacity in

Africa to conduct medical research and led to the successful development of RTS,S. However, few informants could discuss these partnerships without alluding to hierarchy and inequality. For representatives of MVI, they spoke openly about the ways they managed people and motivated trial staff to work. For them, the hierarchical nature of the partnerships may have led to some frictions between people but these issues were overcome. However, for clinical trial staff in Tanzania, some spoke about how hierarchy and inequality meant they were at a disadvantage, lacking the autonomy to build their own capacity for research or benefit from future earnings of the sale of RTS,S. Thus, informants had different perspectives on the partnerships depending on their position within them.

Overall, this chapter illustrates some of the frictions that operate in global health. For the RTS,S vaccine partnerships these frictions related, in part, to hierarchical difference between partners. For Simon, he was in a management position, which may have shaped his perceptions. As well, he appeared to deal with this unequal arrangement by discussing the building of capacity as a positive outcome of the partnership. And for Hassan, he attempted to make peace with the unequal arrangement between partners by thinking of the future. He expressed that although the situation was unequal, he received more than a wage in exchange for his labour; he obtained a chance to be involved in creating a vaccine that had the potential to save many lives, an involvement he felt he would be proud of in the future. Thus, Hassan found meaning in his work for the vaccine trial, making the inequality less problematic for him. In the following chapter, I will build on this finding to discuss people's reflections on the value of the RTS,S vaccine partnerships and trial.

## Chapter 2: Perceptions of Success: Examining Reflections on the RTS,S Vaccine Partnership and Clinical Trial

### Introduction

I spoke to Michael, a representative of the Malaria Vaccine Initiative (MVI), via internet video call in June 2015. Michael compared how medical research had been carried out in Africa in the past with the RTS,S malaria vaccine trial:

I have been doing clinical research for almost 30 years.... Back in the day, we used to call it 'safari research,' where teams would fly in [with] their helicopters. They would do the research, take over the whole place and then blow out of there. They didn't want to leave anything for the physicians and the nurses and the lab people on the ground. We took at the beginning a very different philosophy. We wanted to make sure that we ... were going to leave something there that could be built upon to solve problems. Once after this study was done, [people] needed to be able to sustain that.

Michael emphasized the desire of clinical trial funders to build something that would remain and be sustained after a malaria vaccine clinical trial ended, breaking with the history of extractive medical research in Africa. Michael was not alone in expressing this desire. Although it was acknowledged that RTS,S malaria vaccine had the potential to improve health outcomes amongst African children, the clinical trial staff in Tanzania, malaria vaccine scientists at GlaxoSmithKline (GSK), and clinical trial coordinators/funders at MVI, that I spoke to often asserted that the value of the malaria vaccine partnerships was more than the development of a new vaccine. Many I encountered described the RTS,S vaccine partnership as successful in its ability to "build capacity" in Tanzania, improve the health and education of community members, and create partnerships with communities. For many informants, the aim was that once the vaccine trial ended, these capacities and partnerships could be drawn on in the future to "solve problems", as Michael described it.

As the RTS,S clinical trial and partnerships drew to a close and ended, informants reflected on how activities started and progressed, and what the future held. Informants largely described trial activities, such as capacity building and community engagement, as successful and positive. They may have desired to find meaning in their involvement and wished to affirm that for themselves. At the same time, informants wished to portray the trial and partnerships in a particular way to me during discussions and interviews. Mosse's (2005) writing about a UK Department for International Development (DfID) funded development project in India is helpful for understanding this. Like clinical trials, development projects are intentional activities that have an end. Mosse found that as projects end, people declare whether they were successful or not. But no development project is a success or failure in itself; projects are deemed a success or failure by people who interpret its outcomes and impacts. Policy and program outcomes are often ambiguous and vague, with stated aims such as 'partnership' or 'participation', which are outcomes that are difficult or impossible to assess or quantify. This allows policies and programs to be translated into the goals, ambitions and intentions of the many institutions and people that the project brings together. These people are part of an "interpretive community" (Mosse 2005: 18). An interpretive community is made up of those who judge a project and these people construct stories to assert that a project has achieved a desired impact. Policy need not be implemented and outcomes need not meet expectations. What is needed is enough people who are willing to believe outcomes have met expectations. Thus, the success of project is "not objectively verifiable but socially produced." (Mosse 2005: 172). Drawing on this book, I argue that my informants described the impacts of the research partnership and clinical trial as successful because they were part of an interpretive community.

In this chapter, I explore the ways informants deemed the vaccine partnership and trial successful and beneficial. I focus on several outcomes of the trial high-lighted as successful by informants, including the construction of buildings, infrastructure and assembly of technology to support trial activities, the training of African trial staff, the provision of health care, malaria control and health education to communities, and community engagement. I elucidate the connections that informants made between research and partnership, untangling the entwining of these projects: one to test a new vaccine and the other to build capacity and foster partnership between North and South, and between researchers and communities.

I then analyze why informants portrayed the partnerships and trial as successful and beneficial to people and places in Tanzania.

#### The Value of Medical Research

As Michael alluded to above, during the colonial and post-independence periods in Africa, Northern scientists tended to collect data from resource poor places and leave, which has since been termed "parachute" or "safari" research. This way of conducting research is now perceived disapprovingly in global health circles and Crane (2013) argues that global health researchers tend to be acutely aware that earlier international medical research was conducted under dubious ethical conditions. Instead, global health organizations and researchers now advocate for partnerships with institutes, researchers and communities in resource poor countries. This is perceived as a more equitable approach to international research. With this shift towards partnership, there is an emphasis on and commitment to building capacity and forming collaborative relationships with local researchers and communities (Crane 2013; Kelly and Geissler 2011). Thus, medical research partnerships have increasingly aligned their agendas with philanthropic organizations and global institutions which have recently come to prominence after public health care systems collapsed in many developing countries. International science now often explicitly claims to contribute to the public health and research capabilities of resource-poor countries (Street 2014; Crane 2013).

Framed as "capacity building", these activities can include material outcomes, such as infrastructure, health care provision, career training and employment (Simpson and Sariola 2012; Geissler 2015b; Kelly and Geissler 2011). These often form standard features of medical research in low-income settings. Such activities enable the conduct of medical research in the places where the resulting medical knowledge will be employed but they can also serve as way to add value to research activities and build partnership with local researchers. The building of capacity demonstrates corporate social responsibility and aims to extend the benefits of research past pharmaceutical companies or research partnerships to the resource poor places where research is carried out (Kelly and Geissler 2011; Street 2014; Geissler 2015b; Leach and Fairhead 2011).

In addition to capacity building, international medical research partnerships and pharmaceutical companies aim to establish partnerships with communities impacted by research through activities called "community engagement". When research is conducted with vulnerable groups, important ethical considerations are raised. This includes questions about participants' understanding of the research, the level of voluntariness or coercion in people's decisions to participate in research, the potential to exploit research participants, the social value of the research, and the sharing of research benefits (Emanuel et al. 2004; Chantler 2012). Community engagement is the process of enacting two-way communication between research communities and researchers. Various international guidelines emphasize the need for community engagement in resource poor setting because these activities can ensure that communities understand the procedures and purpose of research, and it can enhance trust (Nyika et al. 2010). Community engagement and partnership can also allow lay citizens to shape the management, orientation, and evaluation of research (Kelly and Geissler 2011). If partnerships with communities are not established, the fear is that

> [e]xclusion of ordinary members of communities from which participants are drawn, over and above local beliefs and cultural practices, could create conditions that are conducive to the generation of misconceptions, rumours and suspicions about particular research projects, which could deter potential participants from taking part in the research or could hinder the progress of the research (Nyika et al. 2010: 86).

Community engagement between communities and researchers is proposed as a standard for ethical research, as well as a tool to address ethical concerns (Chantler 2012; Emanuel et al. 2004). Community engagement and establishment of partnerships represents a shift in ethical doctrine towards the consideration of community perspectives and social practices and entangles medical research in the local context (Kelly and Geissler 2011).

Like capacity building, establishing community partnership through engagement is conceptualized as way to add value to medical research (Kelly and Geissler 2011). Petryna (2009) has noted that recruiting and maintaining research participants is expensive and time-consuming but is equally important to establishing and maintaining technical facilities. Collaborators and funders increasingly demand documentation that a research centre can recruit participants (Okwaro and Geissler 2015). Research centres with strong partnerships with communities can attract researchers and pharmaceutical companies to the area for future medical research. This in turn is thought to benefit communities through further provisions of health care and capacity building through successive research studies.

Informants reflected on capacity building, benefits sharing, and community engagement when discussing the RTS,S vaccine trial. These activities were central to how people understood the trial and its value. Below I explore informant's narratives about these activities.

## **Buildings, Infrastructure and Technology**

In order to conduct the RTS,S vaccine clinical trial, investments were made into the building of capacity in Korogwe. For many I spoke to, the construction of infrastructure and buildings, along with the provision of technology, were important forms of capacity building. Dr. Joe Cohen, the co-inventor of RTS,S, discussed capacity building when I spoke to him on the telephone in 2014, when he was in Belgium and I was in Dar es Salaam. He said, "I think a lot of health infrastructure in and around the villages have benefited from the trial. We hope that will remain and has had a positive impact on the community around the trial site." He also said:

There was a lot of ... so called 'capacity building', in terms of training of ... research and medical personnel.... At all these sites, quite a bit of training of their staff was done. Quite a bit of new equipment was being brought to the sites so they could do the kind of testing that was required. A lot of capacity building in terms of building laboratories. And these are not just laboratories, four walls and that's it. These are really ... in all the cases, are high standard science laboratories.... In the local hospital, a special ward was built to house kids that participated in the trial. In all of these places, X-ray machines were provided and the training that goes with it.... All is not rosy of course ... but ... in general [the vaccine trial employees] recognize the enormous capacity building ... and how positive that has been for them and the community around them.

Thus, Dr. Cohen viewed the building of infrastructure and capacity as a largely good thing and assumed many others did as well.

Sharon, a representative of MVI, had been involved in the phase 3 RTS,S vaccine trial from its inception and spoke about the building of capacity for the vaccine trial when I interviewed her via internet video call in 2015. She said, "We

sponsored a lot of ways for the capacity building, the education, the training". Sharon explained that the Korogwe trial site received the most amount of investment out of all the 11 RTS,S vaccine trial sites in Africa. There had been very little at the site prior to the phase 3 trial because the phase 2 RTS,S vaccine trial had been conducted out of the Korogwe District Hospital. When the contract was received to continue with a much larger phase 3 trial, the Tanzanian investigators knew they would need more space.

Joseph, a trial administrator and medical doctor, explained how infrastructure was built in preparation for the phase 3 trial:

[W]e had more than 1,500 kids involved and we did not want to have to disturb their routine health care provision system. Because if we could use the same buildings or ask for space to be allocated for conduct of the trial then we could probably compromise the service that was being provided.... So, we discussed with the sponsor [MVI] and the sponsor had another NGO established called MCTA, Malaria Clinical Trial Alliance. That was mainly funded to support sites in developing infrastructure. So, we got funds from this Malaria Clinical Trial Alliance for us to build new structures for these nine dispensaries. The local government, the district medical officer allocated a piece of land to be built ... close to the government health facility to support the clinical trial and that's how the arrangement was made. We supervised the construction locally and you had to make sure that the furniture [was] installed to make sure that we had a conducive environment for conducting the clinical trial using [trial] dispensaries.

The funding from the MCTA included money earmarked not only for the building of dispensaries but also state-of-the-art spaces for research, the transfer of technology, setting up of laboratories, and establishment of virtual networks for communication and the sharing of data at the Korogwe Research Centre.

I spoke to Simon, the site coordinator at the Korogwe Research Centre, one afternoon. He expressed his pride of the investments into infrastructure in Korogwe. Remarking about the laboratories, he said, "we are in a developing country and getting such a laboratory like the one in Korogwe, you cannot find many in this country, there are very few. We are privileged because our ... donors decided to establish this lab here in Korogwe." With this, Simon expressed the idea that Tanzania was lagging behind other places in the world and that the setting up of spaces such as an internationally recognized laboratory helped improve Tanzanian development and create opportunities for further research. He was also expressing

the shrewd ability of researchers to establish partnerships and draw funding from transnational organizations to establish the laboratory in Korogwe.



Figure 4: Trial dispensary.

Several trial staff members related the building of infrastructure to improvements in health care delivery for both trial participants and the surrounding community. I interviewed Wilson, a laboratory technician, one afternoon in the conference rooms at the Korogwe Research Centre. He had just been working in the laboratory and was still wearing his white laboratory coat as we discussed his involvement in the vaccine trial. Speaking about the impacts of the trial, he said, "The infrastructure was built to conduct the trial so that is something that will be left behind.... That has improved care, especially for children who are treated at the hospital." He was proud of the achievements of the trial, expressing that they not only helped improve the health of the children in surrounding communities but were lasting impacts of the trial and the vaccine partnership. Simon also spoke about the building of health care infrastructure: "The RTS,S project has built some ... dispensaries that are based in our study villages. By the time the project ends, those properties will remain in the hands of the government. That infrastructure will be the property of that community, of the village government, of the particular areas." Each of the vaccination dispensaries built for the trial were brighter, newer and cleaner than any government dispensary or hospital in the area and came

equipped with wooden furniture used for the running of the trial. These formed parts of the investments in the area that lasted past the end of the trial.

One morning I interviewed Ibrahim, a data manager, in the conference room. He spoke quietly and provided background on the phase 3 trial activities and his work in the data management offices in the basement of the Research Centre. Speaking about the positive impacts of the trial, he said, "we have a good laboratory. The equipment, personnel, technicians are very good.... It helps the community [that] we're here." Grace, a laboratory technician, mirrored these sentiments one afternoon as we sat in her small office at the Korogwe Research Centre. Grace spoke about the legacy of the RTS,S trial: "The infrastructure was built to conduct the trial so that is something that will be left behind. The infrastructure helps other researchers to come in".

Capacity building can take different forms but for several informants, the buildings, infrastructure and technology constructed and set up to conduct the RTS,S malaria vaccine trial in Korogwe were positive and beneficial impacts of research partnership and clinical trial. Through the construction of buildings and setting up of infrastructure and technology, the Korogwe Research Centre provided an opportunity for Africans to do cutting-edge research. As well, these buildings were thought to help improve health care provision for trial participants and community members while the trial was ongoing, which Wilson discussed above.

Importantly, these material constructions were left behind in Korogwe after the trial ended. Through the material objects originally built for the vaccine trial, the potential opened for future medical research to be conducted in Korogwe and the improvement in health care delivery to be continued past the end of the trial. Thus, the infrastructure, buildings and technology not only supported the development of a malaria vaccine and improved health care provision but also could be called on to develop medical interventions and provide health care in the future. For these reasons, several informants viewed the partnership and vaccine trial as great successes in building sustainable research and health care capacity.

These materials also played a role in partnership. The buildings, infrastructure and technology enabled people to conduct internationally recognized research. This was, as Simon alluded to, not abundantly available elsewhere in Tanzania. The ability to work in and with such objects drew in researchers and other staff to partner with GSK and MVI and work at the Korogwe Research Centre. For example, I spoke to Nathanial, a laboratory technician, one afternoon in the

haematology laboratory. He reflected on the laboratory equipment: "I am so happy to work in this laboratory, with these machines. They are so new and advanced, more than anything you would find in the laboratories run by the government." Since trial staff personally benefited from this kind of capacity building, and saw communities benefiting as well, they portrayed the buildings, infrastructure and technology as successful impacts of the vaccine partnership and trial. At the same time, as the trial was ending, staff may have desired to highlight the more permanent impacts of the trial, including the buildings, technology and infrastructure.

#### The Training and Employment of Staff

Although the RTS, S vaccine trial built material and technical capacity, several informants spoke about the building of a different kind of capacity. For many, capacity building also involved training and improving people's abilities to do new kinds of work. Commencing in 2009, the RTS, S vaccine partnership invested in building human capacity by providing specialized training to the over 100 trial staff members in Korogwe. This training improved the ability of Africans to carry out the large-scale clinical trial at an international standard. Doctors were trained to enrol participants in the vaccine trial, handle evidence and fill out paperwork. Laboratory technicians learned new techniques for analyzing tissue samples and received special certification to conduct internationally standardized diagnostic tests. Data managers were trained to enter data into a new computer program and to 'clean' the data to remove mistakes. And fieldworkers who were hired to live in study villages during the trial received training in first aid and rapid diagnostic tests, as well as how to engage with communities. At the beginning, and every two years thereafter, staff were trained in the procedures of Good Clinical Practice Guidelines (GCP). GCP is a set of global standards that staff had to adhere to for the data collected over the course of the trial to be comparable across the 11 RTS, S trial sites in Africa (Simpson and Sariola 2012). Additionally, each staff member was instructed in how to interact with communities and trial participants. As Erick, a trial fieldworker, explained one afternoon while interacting with research participants at a trial dispensary, "trial staff are trained to treat participants with care and respect."

The training of East Africans to conduct the trial was a departure from the phase 2 RTS,S vaccine trial. In that previous trial, many of the people carrying out

the trial were from Europe. Speaking to Simon, he provided some background on the previous RTS,S trial. "All the offices were occupied by the experts from Europe for coordination, data, lab. Even the PI [Principal Investigator] was from Europe." Simon continued: "By the time this project was initiated, there were very few Tanzanians who were able to do this kind of work." Although the phase 2 RTS,S trial was largely conducted by Europeans, for the phase 3 trial, none of the staff members originated from outside of Africa. Out of around 100 staff members, all but two staff members came from Tanzania, with the other two originating from neighbouring Kenya. Simon explained that this shift towards more local staff was to improve employee retention, since it was thought local staff would be more likely to stay on throughout the entire trial. It also gave East Africans the chance to run a large-scale trial. Tom, a British malaria researcher involved in a West African RTS,S trial, reflected on this: "[F]or the African investigators this [trial] has been a wonderful opportunity to learn things on the ground."

More than having the opportunity to gain new skills and learn, the RTS,S partnerships made it possible for African researchers to obtain funding for postgraduate programs. Tom said, "I'm sure, if you look at the end there will be quite a few people who will get a Master's or a PhD through the trial.... They wouldn't have been able to do that if they hadn't been funded by GSK and MVI. So, I think indirectly [the trial] has provided opportunities." At the Korogwe Research Centre, a laboratory technician completed a PhD in molecular biology at a French university and another laboratory technician completed a PhD at a university in the United Kingdom. These two laboratory researchers had worked at the trial and simultaneously carried out scientific research by collecting data about children admitted to the Korogwe District Hospital. Also, Simon completed his Master's at a Tanzanian university by conducting research about the RTS,S vaccine trial<sup>18</sup>. In these cases, the trial and the vaccine partnership was beneficial to these individuals, opening opportunities to advance their careers.

Beyond learning new skills or obtaining advanced degrees, the trial allowed staff to earn a good salary. Hassan was a trial fieldworker I interviewed in the

<sup>&</sup>lt;sup>18</sup> Permission for these ancillary research projects was granted by the Ancillary Study Review Committee (ASRC), a committee established by MVI, GSK and the African clinical trial sites. The application for ancillary research went through an application and review process and required ethical review by an institutional review board (IRB) in the home country and Tanzania. The laboratory research drew on data collected for the trial while the social science research was

conference room at the Korogwe Research Centre one afternoon. He related the salary employees received to improvements in Tanzania: "The salary we [staff] are being given, it helps us as Africans and as a community." For some, this salary allowed them to invest. For example, Hassan was saving his salary to attend medical school and Wilson used his salary as a laboratory technician to buy land and build a house in Korogwe. Denis, a trial driver, said he invested his salary into educating his children at a private school. Thus, the establishment of partnerships with organizations from wealthy countries opened opportunities for trial staff that would not otherwise have been possible.

Through the RTS,S vaccine partnership and clinical trial, human capacity was built in Tanzania. Trial staff obtained training in health care provision and research and some obtained funding from partners to attend post-graduate programs. While the trial was ongoing, staff expressed an appreciation of the salary they received, which helped them, their families and extended social networks, which Hassan spoke to. Many were also pleased that they obtained training that could allow them to conduct clinical trials or work in different health care or policy settings in the future, something I will discuss further in chapter 3.

Overall, some informants viewed the training of Africans as an important value of the vaccine partnership and clinical trial. This training had the potential to strengthen the Tanzanian workforce and improve the ability of Tanzanians to provide health care and conduct research. Trial staff deemed the building of human capacity as successful and positive because they each personally benefited from their affiliation with the RTS,S vaccine partnership and trial and wanted me to see the positives. As well, as a majority faced unemployment, they may have wished to look to the future impacts of capacity building on Tanzania, beyond the RTS,S trial. However, unlike the buildings and infrastructure constructed for the RTS,S trial, people had the ability to move and leave Korogwe, or even Tanzania. Thus, the human capacity built for the trial was mobile. This issue complicates the narrative of success put forth by informants, an issue that will be discussed in further detail in chapter 3.

carried out amongst the caregivers of participants, community members or trial staff, as was the case with my own research.

# Health Care, Malaria Control and Health Education

Informants identified additional positive impacts of the RTS,S partnerships and vaccine trial, including the provision of health care, malaria control, and health education. For the health care, this included the provision of free emergency transportation and medicines to those willing to participate and some of these services were also made available to children in need who were not participating in the clinical trial. Health care was provided in the pediatric ward of Korogwe District Hospital and trial dispensaries by doctors, clinic officers and nurses that worked for the RTS,S trial. Simon described these services and their impacts:

> We are not only working for participants involved in the malaria vaccine trial but also across the community.... You can find that a parent that has a child in the study, sometimes he or she came to a dispensary accompanied with other children. For example, a mother that has other children and she came to our clinic and we find all the children are sick.... [W]e cannot discriminate and say we will only treat the one participating in the study. We tried to see how the project can make sure that the other children are being helped. We have done this for some time and the community is quite appreciative.... [W]e are also supplying medication in the pediatric ward of the Korogwe District Hospital, which is admitting all people in the community who are under five [years old]. We supply medication ... because of the status of the country's economy, sometimes it is not easy to find medicines in the pediatric ward.... One of the wards that is performing the best is the pediatric ward because the ... staff in the pediatric ward ... are 100% paid by the trial. They are providing medical care to whoever is admitted to the ward, regardless if they are participating in the trial.

The practice of providing health care to children in need was supported by the trial funders, as Sharon explained:

[W]e knew sometimes ... that if a trial participant's brother or sister got sick that we had to put into the budget that we would also be giving if there were stock outs of medicine, that we were providing that resource for the family. That was hard explaining to the people that are sitting in a fancy office, trying to explain that we have a mother that has a sick child and there was no medicine at the dispensary. That was all part of the whole mission driven nature of this.

Along with health care provision, the vaccine trial provided malaria control. Improvements in health care provision, including early detection and treatment of malaria amongst community members, was key to this control. Additionally, each trial participant received a free insecticide-treated bed net. Trial staff provided these through a donation by the Tanzanian government, with funds stemming from global health donors. Simon spoke about the impacts of the trial on malaria control: "By the time we were planning this study, we promised a bed net for each individual who participated in the trial. Keeping in mind that our mission is not only ... the malaria vaccine but we wanted to see to the well-being of the community, to make sure that the child is protected."

Both Sharon and Simon referred to the RTS,S trial as a "mission". They were espousing the viewed that the work they did was important for more than bringing a drug to market. This expression uncovers that these informants viewed their work as more than a salary, that it provided them with a sense of meaning because they saw themselves as helping people in need, even if temporarily. Many people involved in the trial thought of their work in a similar way.

Beyond health care provision and malaria control, several informants discussed the role of the vaccine trial in improving health outcomes in communities through health education. Several put forth the view that trial staff played a role in educating communities about their health and the need to prevent and treat malaria. As Dr. Cohen said, "The trial has had an educational effect on the population because the doctors and nurses have discussed the trial, malaria and health more generally with the villagers, the elders of the villagers and the population."

I spoke with Hassan who said,

[B]efore we were here, people died of malaria, there were a lot of cases of malaria. But after that, not only did we help them with malaria but we gave them the right information about how to fight malaria, on how to use bed nets and this information was not only given to participants but when we were doing the village meetings we were telling this to everyone. We told them that, even if you're being vaccinated you should use bed nets. You see? Things like that, the right information given to them at the right time, it might help. And this helps to decrease the rate of malaria in the area.

Nathanial, a laboratory technician, also discussed the provision of health education when I spent time with him in the haematology laboratory at the Korogwe Research Centre one afternoon. Nathaniel, wearing a white laboratory coat and latex gloves, was creating blood slides, drawing a bit of blood from a small vial and smearing a thin layer of it across a small piece of clear glass. Looking out the laboratory window to the pediatric ward of the Korogwe District Hospital, Nathanial recalled that a trial participant had come into the hospital vomiting black liquid. Health care providers could not give the child quinine to treat the malaria that he had, they feared the drug would react badly to the herbs he had been given by a traditional healer and kill him. Nathaniel said, "I think a lot of children die because they are taken to traditional healers". Nathaniel asserted that fieldworkers were instrumental in communicating to caregivers of trial participants to not to make use of traditional healers. He spoke about community members, saying: "These people are uneducated. But the fieldworkers are educating them, telling them to take their children to a dispensary when they are sick."

Hassan shared his thoughts on traditional healing practices:

Sometimes a child is sick, maybe with malaria, high fever and a traditional healer wastes time.... But the fever goes up and up and when they finally get here [to the hospital] they give the physicians a lot of work. So, we told them, when you see a child is sick, especially with fever, *never* take the child to a traditional healer.

Hassan also discussed how trial staff dealt with people making use of traditional healing practices:

Every time we see the child we ask, 'Has this child seen a traditional healer? Has he had concomitant medication? You have to report this to us because it might affect the child'. So, some of them are ashamed to tell us but most of them are ashamed to take the trial children to the traditional healer because we tell them that we believe we can help your child in every way so you don't have to take your child to a traditional healer. We are giving them information that a traditional healer can't help you; this child should be taken to the hospital.

The fieldworkers I spoke to often described their work in the communities as a form of education. As Hassan said, "not only did we help them with malaria but we gave them the right information about how to fight malaria, on how to use bed nets, and this information was not only given to participants but when we were doing the village meetings we were telling this to everyone." Also, community members were told by fieldworkers and other trial staff to take their child straight to a health care facility at the first sign of fever to avoid death due to malaria, which is fast acting and can kill young children within 24 hours (Trampuz et al. 2003). Hassan expanded on this point: [B]efore we were here the mortality rate was quite high, a lot of children were dying. It might not be malaria but they died because of the ignorance of their parents, they did not take them to the health centre at the right time. [But] they saw how we treated them and they copied that.... They told their fellow people about how we got them treatment. ... So, the information given was going to everybody and helping them in the area.

Erick related trial activates to education: "We use it [trial activities] as [a] means of giving people education so that they can understand how to live a healthy life, how to maintain their environment." Ibrahim, a data manager, also spoke about the educational effect of the trial, describing how community members came to understand through trial staff the need to cut back grasses and not allow standing water to form around their homes, in order to discourage the breeding of mosquitoes that carry malaria.

From the perspective of several informants, there was a lack of good health care and health education in communities in and around the town of Korogwe. To fill this gap, the vaccine partnership and trial successfully provided improved health care, malaria control and health education to communities. These activities were a mechanism to distribute resources to those who had no other way of accessing them.

However, although these activities and provision of material resources were portrayed as benevolent, they were necessary for ethical reasons. As described in the introduction, randomised control trials must adhere to international ethical codes and guidelines. These codes stipulate that the placebo group of a clinical trial must receive the best treatment and forms of prevention currently available (Angell 1997; Sariola and Simpson 2011). One of the best ways to prevent malaria is through the use of insecticide-treated bed nets and thus, their provision to trial participants allowed the trial to uphold ethical standards (Khatib et al. 2008). As well, medical research conducted in resource-poor settings must also include the provision of a high standard of care (Sariola and Simpson 2011; Angell 1997). This means that while informants portrayed health care and health education as beneficial to communities, they were also instrumental and served the needs of the vaccine partnership and trial. At the same time, informants were thinking back over the course of the clinical trial and desired to focus on the positive aspects, including how the trial gave back to communities by providing health care, resources and education.

## **Community Engagement**

Trial staff spoke of another positive impact of the RTS,S vaccine partnership and trial: the establishment of relationships with people living and working around the Korogwe Research Centre. These relationships were formed with a range of people on the ground in Tanzania, from hospital administrators, district medical officers, community leaders to community members. However, trial staff tended to focus their accounts on the building of relationships with people in the villages and towns that were impacted by the RTS,S clinical trial.

Relationships between trial staff and communities were built through a series of meetings and communications, which trial staff called "sensitization" and bioethicists term "community engagement". As the bioethicists Emanuel et al. (2004) have argued, community engagement and the establishment of partnerships minimizes risks of exploitation, ensures the fair distribution of benefits, and improves the informed consent procedure. In Korogwe, RTS, S vaccine trial activities commenced in 2006 in preparation for the phase 2 trial, which occurred from 2007 to 2008 (Olotu et al. 2011). Trial activities continued into the phase 3 trial, which ended in 2014. Trial employees regularly engaged with community members throughout the two phases of the vaccine trial but the most intensive engagement occurred before phase 2 and 3 began and during the first few months of the two trials, when children were being vaccinated. I was not present in Korogwe at this time but people recounted their interactions with community members when I arrived in Korogwe in 2013. This recounting shed light on how trial staff perceived and negotiate relationships with community members throughout both phases of the trial. As will be discussed below, informants often claimed community engagement was successful. These activities were portrayed as not only leading to community acceptance of medical research and a speedy enrolment of participants in the two vaccine trials, but also as benefitting community members in various ways, which will be discussed below.

In order to conduct both phases of the RTS,S trial, trial employees carried out censuses of villages. These censuses helped staff identify children and pregnant women who were close to giving birth and who fit the inclusion criteria of the trial. The inclusion criteria stipulated that the child had to be within the study age range of 6 to 12 weeks for the younger cohort of participants, and 5 to 17 months

old for the older cohort, and healthy with no pre-existing conditions, like HIV (human immunodeficiency virus).

Once the censuses were completed, trial staff had a series of meetings, or sensitization, with community members. Simon had a lot to say about sensitization, having been very involved in the process during both phases of the trial. "[T]he first thing we did was sensitize the village leaders and influential people in the community.... We brought them together in a meeting and we explained ... the final aim of what we're doing and how the community would benefit from the trial." These village leaders consisted of religious leaders, elders of the community and elected officials.

Later, meetings with community members were held in villages. Simon explained the role of community leaders in these subsequent meetings:

By the time we conducted the village meetings, we had these village leaders who were aware of what we were doing. They were the ones that organized those village meetings and in case of questions from the community, they were the ones to answer the questions. So, the community built trust in us because we are following the right official government channels.... And those leaders were telling them that it is good for them to join.

Although laboratory staff rarely visited the villages that were involved in the trial, Grace had been very involved in community sensitization out of a desire to connect with and understand the people impacted by the trial. She attended many of the sensitization meetings and described the process:

First, we made a date, an appointment, and then we all [went] there together. Then we just [started] talking, saying who we are, what we want to do, the pros and cons of participating and then they [community members asked] questions, doubts, anything ... then we [went] to the village looking for participants and there [were] those that agree [to participate].

Thus, the sensitization process informed community members of research activities, informed them about the purpose and benefits of the vaccine trial, and attracted interest amongst caregivers to enrol their children in the trials. From what Simon and Grace said, these meeting helped create trusting and collaborative relationships, opened a two-way dialogue between the trial staff and those living in areas impacted by the research, and allowed people to ask questions. These

meetings also served as a preamble to informed consent by providing information to the caregivers of potential trial participants.

Although Simon described the sensitization process as straightforward, Grace discussed difficulties with developing relationships with community members. I first met Grace at a medical research conference in Arusha, Tanzania in 2012. She had just finished presenting a paper and I asked her about her experiences of the vaccine trial. Grace explained that during the second phase of the trial, community members had started rumours. This piqued my interest and when I had a formal interview with her in her office at the Korogwe Research Centre in 2013, I asked her more about the rumours. Grace said, "for [the] previous ... phase 2, there were problems, it was difficult. People had to get used to us because sometime they say ... you just take blood, you don't do anything." Grace recounted that some community members feared that the trial staff were "vampires and we take blood", blood that was then sold in Europe. Grace explained that some community members did not trust trial staff so they did not enrol their children in the trial. These rumours persisted over time, as Grace explained: "Even the people here [in] the next village, some still believe we are vampires and they are scared to even cross by this building [the Korogwe Research Centre]."

Grace then described how trial staff and community leaders built trust with community members to encourage enrolment into the trial. "We ... cooperate with village leaders in case ... there is something misunderstood or rumours about our study. We used their leaders to explain to them that really, we are not bad." Later she said, "You sensitize [community members], you say no, [the rumours are] not true. And some of them they get sensitized by their neighbours who understand."

During an interview with Hassan at the Research Centre, he also spoke of rumours and how they were overcome. He said, "some people were saying that they were given poison, that they were poisoned." Hassan explained this in more detail:

We had problems recruiting participants because when we go there and greet them, we tell the people what we are doing with the project, that the vaccine will do this and this and this. When we went away, some other people tried to twist the information.... So, the information that [those people] gave the participants was not good information. Participants then had a lot of doubts. Our job as fieldworkers then was to keep away those doubts with the best information we had. Before we went there we had meetings, we were told how this vaccine was made. Even the [inventor, Dr. Joe Cohen] who made the vaccine ... came here, we had a chat with him. He told us about how he invented the vaccine, for how long he stayed in the lab. We really had a lot of information on the vaccine. So that helped us clarify a lot of the issues we had about the vaccine.... [Community members] were given wrong information so what we did is we clarified. It is true that this was seen as just a trial but it [RTS,S] underwent a lot of phases until it was administered to people.... Another thing we told them is that this small group of people who volunteered to participate would help us to help [many] Tanzanians. So, people are willing to help on behalf of other people.

Erick had begun working at the Korogwe Research Centre during the phase 2 trial and become a fieldworker supervisor during the phase 3 trial, serving as a bridge between trial administrators and fieldworkers. I interviewed him one afternoon in the conference room of the Research Centre and he recalled the sensitization process during the phase 2 RTS,S clinical trial:

From the beginning, we experienced a lot of challenges.... [W]ith people, there is a lack of proper knowledge about the study because some people thought we were not as we say we are, that we are here to collect ... and sell their blood. Others said that these people are not good, why do they treat you for free? They give you free transport and you don't pay anything. Are they good? So, from the beginning ... there were several drop-outs.

To overcome this, Erick said trial staff "conducted several sensitization meetings, giving them proper knowledge about what is a vaccination trial.... [T]hey become familiar with our project and the work.... It's fine at this moment."

During my interviews with Grace, Hassan and Erick, each attributed the rumours to ignorance, and a lack of knowledge and trust. From their perspectives, the rumours were a passing issue remedied with more meetings with community members, trusted officials vouching for the good intentions of trial staff, and the provision of more information. These trial staff explained that by taking these steps to build relationships with communities led to an increase in acceptance over time. As Hassan said, "with [phase 2] we had problems but with [phase 3] people were just referring to what we did in [phase 2] so it wasn't that hard to recruit people because they knew we were giving the best service ever given to these people here and they appreciate that." Referring to community engagement activities during the third phase of the trial, Grace said, "We were received positively." Over time, there was even demand amongst people to participate in the RTS,S clinical trial. Grace

explained that after the trial began, some community members said to trial staff that they wished they had not doubted the trial and enrolled their child when they had the chance. As Grace said, some even wished to enrol more than one child in the trial. "We had people want to get in but the recruitment already closed. If a mother has a child that is in [the trial],... then she gets pregnant and says, 'I even want this one in the trial' but [we] would say, 'No, it's not possible because recruitment has ended'."

Another staff member spoke about community engagement as successful. Joseph had been involved in the phase 2 and 3 RTS,S trials and when we spoke in the conference room, he summed up community engagement activities: "[E]ven in areas where we didn't have the phase 2 trial, still the participation and acceptability rate was high. So, the main thing that I saw was the way we did the sensitization, the approach of the study to the community. So, that is one of the main reasons we succeeded." Joseph defined success as the ability of trial staff to conduct sensitization and enrol participants into the trial.

Simon also spoke about success, the overcoming doubt and building trust with communities:

When you go to the community and you say you have a new vaccine that you need to test and you say you are testing it to the people who are not ill, [it] is a bit difficult to understand for common people from the village. Telling them, can you bring your child to test our vaccine, it is not that easy. I could really understand their hesitations and doubts because if it is you, you need to sit down and get enough explanation so you know that this thing has been monitored by international people and ... to make sure that we are not harming the community.... We were very successful because the community was happy with us and they are happy to continue working with us.... We were able to assure the community that what we were doing was positive, that is was for the benefit of the community, especially when we have the vaccine.

Simon and other staff attributed the successful enrolment of participants to their community engagement, provision of information, and communication of the benefits of research to people living around the Korogwe Research Centre. This provision of information not only improved community acceptance and enrolment into the trial but was portrayed as helping communities overcome general ignorance about science, medicine and research, an added benefit of the vaccine trial.

Although some trial staff described the success of community engagement by referencing the rumours spread amongst community members and how they were overcome, there is another way to understand these rumours. Geissler and Pool (2006) wrote about their experiences of medical research in Africa and the spreading of rumours and supplemented their experiences with reports from 29 researchers and colleagues involved in medical research across Africa. In this article, the authors describe several kinds of rumours but I focus on the rumours about blood stealing and vampires, which may help explain the rumours about the RTS,S trial.

Geissler and Pool (2006) found that that beliefs about vampires and blood stealing are often attributed by medical research staff to "traditional beliefs", like the supernatural and witchcraft. The authors contended that although many rumours likely stem from pre-colonial African ideas about the supernatural, this explanation implies that these beliefs are irrational and limited, and that they will eventually be replaced by modern, rational knowledge once people become educated and developed. However, this explanation posits a simple idea of 'modernization', whereby one modern and scientific rationality exists at the end of historical progress. Although ensuring that research communities understand the procedures of medical research can improve acceptance, a lack of knowledge does not fully explain why rumours are spread. This is because rumours can occur in places where there are higher levels of education, such as in cities, and they can occur in relation to familiar interventions, like injections, which have been part of African health provision since the colonial era (Geissler and Pool 2006; Vaughan 1991).

Geissler and Pool (2006) argue that although vampire and blood stealing rumours can relate to traumatic colonial encounters, they are rooted in the present. The rumours about blood stealing are a way for local communities to use their own terminologies and models to debate and express their concerns about medical research. As blood is often viewed as a source of wealth, the rumours can be a critique of the unequal distribution of benefits available through science. Rumours about blood being stolen by researchers for their own gain speak to a sense of colonial and post-colonial exploitation and inequality. It also allows expression of and debate about the ambivalence of research participation, related to the advantages (which is usually free treatment) and the disadvantages (giving bodily tissues, like blood). The rumours of blood stealing thus often represent medical research as an activity that extracts more than it gives and speaks to a desire on the part of locals to see the benefits of research circulate more widely in research communities. Although some community members in Tanzania changed their minds about joining the trial, the rumours of blood stealing and vampires may speak to a problematic relationship between researchers and the community. For community members, rumours can indicate a level of ambivalence towards medical research and a desire for greater benefits from the research. Not taking the rumours seriously and addressing them could prevent dialogue between communities and researchers and could hinder future research from being conducted and research findings from being implemented in the future (Geissler and Pool 2006). However, although there is an alternative way of understanding rumours of blood stealing, the RTS,S trial staff I spoke to largely viewed the rumours as a sign of ignorance and something that decreased when people received more education about medicine and research activities from trial staff. Thus, instead of questioning these rumours or thinking critically about them, trial staff understood this situation as having a positive outcome.

Once community engagement was carried out and staff felt they had established collaborative and trusting relationships with communities, follow-up meetings were carried out with individual families. Explaining this next step, Simon said,

[F]or those individuals who were selected to be in the study, we also had house-to-house sensitization for the family. So, if they need more information ... we had a mechanism to go house-to-house and educate, clarify or answer questions that people felt shy asking in front of the public.

After this stage, staff attempted to attract people to enrol their children in the vaccine trial. First, trial employees delivered invitation cards to the caregivers of children who were identified as potential participants. These invitation cards directed caregivers and children to visit the trial dispensaries closest to their home at a particular day and time. Caregivers who arrived at the vaccination dispensary the day they were invited would receive information about the trial, including an explanation of the risks and benefits of joining. At that time, caregivers had the opportunity to speak to trial doctors and administrators privately and read the consent form in one of the rooms of the trial dispensary. If caregivers agreed to enrol their child in the trial, they signed the consent form. If the caregivers were illiterate, staff read the consent form aloud to them and a trial employee would serve as a witness as the caregivers signed an X on the signature line of the consent form. Although the focus during sensitization had been on obtaining community

acceptance, when it came to obtaining consent for medical research, the ethics focused on individuals. This consent process depoliticized ethical debates about transnational medical research and instead focused on the following of rules and filling out of forms to prevent exploitation (Molyneux and Geissler 2008).

Some staff spoke with pride about how the Korogwe Research Centre was one of the first RTS,S trial sites to enrol all their participants ahead of schedule. The speed at which enrolment occurred was often referred to as a sign that community engagement was successfully conducted during the phase 2 RTS,S vaccine trial and that trial staff were able to develop trusting relationships and a sense of partnership with community members. Once participants were enrolled, community engagement continued. Since a fieldworker lived in each of the study villages, they served as the main mediators between the Korogwe Research Centre and trial participants and communities throughout the trial.

While many trial staff that I spoke to described community engagement as the reason that rumours were overcome, Hassan spoke frankly about the role of material resources in shaping research relationships. "We were telling [community members] that we were not paying any parents for participating but there are some benefits that they could get. Like medical benefits, we would treat children until the end, freely. There will be free transport. These things motivated some [to join the trial].... [T]he people from the rural areas really needed this help." In addition, Hassan stated above: "it wasn't that hard to recruit people because they knew we were giving the best service ever ... and they appreciate that." These guotes are telling. Although the rumours may have indicated that communities thought medical researchers were benefiting through the extraction of blood, this may have become less salient as communities received health care and other benefits from the trial. Few trial staff openly discussed this ethical issue, that community members may have accepted the RTS,S trial in order to gain access to health care. This would have undermined prevailing ethical doctrine that requires consent to be provided by autonomous individuals, free of coercion (Geissler 2013).

More than shaping acceptance of the vaccine trial, community engagement—along with the provision of material resources—may impact future research endeavours. Simon explained: "the community, they can have high expectations and if you don't meet their expectations they might jeopardize your work in the community. If this happens, you are creating a bad future. If you don't meet the community expectations, it can make it difficult to return for another study."

Thus, meeting community expectations may facilitate drug companies and medical research organizations entering the area in the future. This made it critical that RTS,S trial staff took their interactions with community members seriously, as future research could benefit them personally, bringing future employment.

What Simon said about developing relationships with communities relates to what Nguyen (2005) writes about the establishment of HIV positive communities in Abidjan, Côte d'Ivoire. Accessing HIV drugs was difficult for many Africans in the 1990s. Dr. Dupont, French a HIV/AIDS (acquired immunodeficiency syndrome) doctor who practiced in Abidjan, found that one way to provide drugs and other resources to HIV positive patients was to tap into medical research funds. He set up a laboratory and was able to draw in a community of people willing to enrol in medical research. Dr. Dupont was then able to channel drugs and other resources to these people because they served as research participants. Through the provision of drugs and care to HIV positive patients who had enrolled in research, Dr. Dupont was able to win the hearts and minds of people with HIV and these people were more willing to enrol in subsequent research studies. Over time, he developed a loyal group of people to call on for studies. Simon spoke about relationships with community members in a similar way, as a winning of hearts and minds.

From the censuses, to the sensitization process, to the consent process, many informants deemed community engagement successful. One main outcome of this engagement was the building of collaborative relationships between trial staff and communities. From what Grace, Hassan and others said, formation of this kind of relationship created trust. This trust helped members of the study communities to learn about and accept trial activities, and dispel rumours and misconceptions about research activities, as well as lead to the rapid enrolment of participants into the RTS,S trial. At the same time, relationships between researchers and communities were mediated by material resources. In order to avoid a "bad future", as Simon described it, community expectation for the research had to be met, including the development of an effective vaccine and access to medical and emergency care for trial participants and other children in the community. Provision of these material resources won people over. Hassan claimed that this allowed for the smooth running of the phase 3 trial and Simon explained that this may serve future researchers who come to the area to conduct medical research. Thus, community engagement involved the negotiation of relationships and provision of material benefits that met the expectations of the community.

Another result of community engagement that trial staff touched upon was the provision of education. Sensitization was not entirely smooth and some staff discussed rumours spread amongst community members. Although these rumours may have indicated some dissatisfaction with the unequal relationship between trial participants and researchers, trial staff believed they overcame the rumours through greater engagement, the building of trust, and provision of more information to community members. Importantly, although there was an ethical imperative to engage with communities, when trial staff reflected the community engagement activities, they appeared proud and happy that they connected with community members. Some spoke about how these meeting helped entire communities, not just caregivers of trial participants, to gain a greater understanding of science and medicine. This narrative allowed staff to demonstrate to me, and perhaps to themselves, that they were doing more than serving the needs of the RTS,S vaccine trial, that the benefits of the RTS,S trial extended to communities who were provided with a service.

# Success and the RTS,S Clinical Trial

Michael summed up the accomplishments of the vaccine trial: "There were a lot of naysayers that said that you're not going to be able to pull this trial off in Africa, a phase 3 [trial] of this scale and with the data requirements. So, we did have to take some centres and develop them up to that level but I think ... that the sites and partnerships succeeded." Sharon said:

[T]here are ... legacies that came out of these research centres working with the local hospitals, strengthening ties with the communities. That's [a] long-term legacy ... that will last with the centres and the people in the communities and their country.... There is the big picture, being part of a genuine scientific breakthrough of a vaccine, and then there is the local legacy that will serve the sites well.

Dr. Cohen also described the RTS,S trial as a success:

It's been an enormous endeavour. There was a scientific difficulty but there was also this tremendous challenge of performing clinical trials in the African context under conditions that would withstand all the standards—ethical

and clinical procedure, et cetera—that are applied to any trial you would do in the US or Europe and would actually be robust enough to respond to regulatory requirements. So, we needed to make sure that the trial we were doing would live up to those very high standards. From the first trial we ran in Africa in late 1990s to now it has taken 25 years. An enormous amount of work has been done but most importantly, in succeeding in doing trials that were regulatory proof and were robust and according to regulatory standards

Sharon echoed this:

[P]eople from the West and the North would say, 'Well, it really can't be done in Africa, there will be too many contaminations'. We monitored the labs over the course of five years and ultimately the contamination rates were lower than US lab standards, we have that data.... It was the dedication to excellence.

Having reflected on the various practices and impacts of the RTS,S clinical trial, these three informants considered the partnerships and clinical trial successful, as did many others I spoke to. Many people spoke in certainties but the outcomes of the clinical trial, beyond the development of a malaria vaccine, are difficult to assess and quantify. But informants were part of an interpretive community (Mosse 2005). All gained a salary, skills and improved their resumes, which may allow them to gain future employment. Some staff have become internationally recognized researchers through their partnerships with Northern organizations and publications in international journals. Thus, informants had particular interpretations of the outcomes of success.

At the same time, when I spoke to informants, they were coming close to the end of the RTS,S trial or the trial had already ended. This time evoked a desire to think back over how the trial started and how it operated. Informants may have desired more than to portray events to me, they may have wished to reaffirm to themselves that the trial was meaningful and had positive outcomes. Thus, speaking to me may have been a platform for people to reflect on their experiences of the trial. By focusing on the success of the trial and partnerships, they could tell themselves that the care and labour they provided was worth it and benefited more than GSK or MVI, that it also benefited people and places in Tanzania.

Although scholars debate about what constitutes value in medical research when it is conducted in resource poor settings, many of my informants had clear ideas about the value of the RTS, S vaccine trial in and around Korogwe. Several said that the value of the RTS,S trial was not only its development of a malaria vaccine but its ability to build material and human capacity in Tanzania, improve the health and education of community members living in and around Korogwe, and establish partnerships with communities. When informants claimed to be doing upstanding work in a resource poor setting by providing health care and malaria control, and developing collaborative relationships with communities, they wished to portray their work as ethical and positive. They were demonstrating that they were not just experimenting and extracting from communities in resource poor settings but also giving back to these people and places. As well, many expressed a sense of pride at being involved in a project that may lead to a pharmaceutical product that can save the lives of countless children. Applying Mosse's (2005) term, these people were enrolled in an interpretive community and had their goals, aspirations and intentions addressed by the trial. This meant they had a vested interest in portraying activities and events in a particular way to me.

But more than portraying the trial to me, informants may have desired to tell themselves they had engaged in meaningful work and used their discussions and interviews with me to assure themselves of this. A majority of the staff were on short-term contracts that ended when the trial did and would not gain glory for developing RTS,S or any part of the profit from the sale of the vaccine. Viewing the trial as successful, beneficial and meaningful in its ability to give back to communities and develop a vaccine that may save many lives could have helped informants contend with the end of the trial, its ambiguous outcomes as people waited for the vaccine to be provided, and the unequal relations they had with their Northern partners. While in this chapter I explored informants' portrayals of the vaccine trial, in the next chapter I turn to an exploration of the spatial and temporal limits to capacity building.

# Chapter 3: Building a Legacy? The Ambivalent Impacts of the RTS,S Clinical Trial

## Introduction

With the rise of partnership as the primary mechanism for funding transnational medical research, research institutes explicitly claim to contribute to improving research capabilities and public health care systems in resource-poor countries, which is framed as "capacity building" (Crane 2013; Street 2014; Simpson and Sariola 2012). For the development of the RTS,S vaccine, Northern partners built a research centre in Korogwe, a place where malaria was endemic. As well, several health care dispensaries were constructed in surrounding villages to support trial activities. Along with the construction of buildings and infrastructure, technology was provided and assembled. These material things were necessary for conducting the clinical trial and from the perspective of clinical trial staff in Tanzania, vaccine scientists at GlaxoSmithKline (GSK), and trial funders/coordinators at the Malaria Vaccine Initiative (MVI), these things made positive and lasting impacts on Tanzania. However, observations and discussions with trial staff exposed a more complicated situation when the RTS,S vaccine trial came to an end.

Social studies of science and technology encourage us to perceive material structures and technologies as more than assemblages of metal, concrete or electronic components, but also complex arrangements of meanings, social relationships and knowledge practices (Star 1999; Bijker 2007; Latour 2000). With this in mind, these things can be conceived of as gifts given by Northern institutes. A way to understand gifts is to draw on social scientific writing about gift giving in pre-industrial societies. Malinowski (2014 [1922]) found amongst the tribes of the Trobriand Islands that gift giving led to an inequality between the donor and recipient. The more gifts that a leader was able to give away, the more power they

had, increasing their reputation and prestige. Recipients of gifts became increasingly dependent, which reduced their power. Mauss (2011[1925]) has also written about the spectre of gifts and their economic benefits and costs. Contrary to the general perception that gift giving is separate from economic motives, he argues that gift giving is obligatory and interested. Gift exchanges are frequently rooted in economic and social objectives, which can include expectations of reciprocity. Receiving gifts obligates the recipient to pay back the gift or potentially lose honour, meaning that gift giving serves profitable ends, advancing personal or communal interests (Mauss 2011 [1925]). There are similar concerns about philanthropic and development aid. Donors may claim that their donations to poorer regions of the world are altruistic but gifts can conceal self-interested motives (McGoey 2015).

As these scholars argue, gift giving is a complex social exchange steeped in meaning. In the case of the RTS,S vaccine trial, the building, infrastructure and technology provided by Northern partners were unusual gifts. They were given so institutes could partner and work together to care for these things and develop the RTS,S vaccine until the end of the clinical trial. In exchange for these material things, staff in Tanzania provided data and blood samples to their Northern partners. Although informants at GSK and MVI portrayed these material things as beneficial to Tanzanians, the underlying motive of giving these gifts was the production of a pharmaceutical product that has the potential to make a large profit. Viewed in this way, the provision of these material things may benefit the giver more than the receiver.

But more than this, the end of the clinical trial exposed that these things may be less beneficial than portrayed, as they had uncertain futures. I argue that the buildings and infrastructure had ambivalent impacts. On one hand they enabled medical research and health care provision during the RTS,S clinical trial but on the other hand, they were spatially circumscribed from the surrounding area and their operability was dependent on ongoing funding from wealthy donors. Furthermore, trial staff were obligated to care for the buildings, infrastructure and technology because they were given as gifts that opened the possibility of future partnerships with other wealthy institutions. However, their Northern partners had no such obligations to care for these things once the partnerships ended. Drawing on feminist theory, care can be defined as everything people do to repair, maintain and continue the world so they can inhabit it. This labour relates to the capacity for affect and signifies attention and worry for things that may be harmed. But caring labour is complex, making it difficult to enclose in a schedule or fixed tasks that starts and ends. Despite being vital to maintaining a liveable world, these activities are often devalued, taken for granted and considered unimportant while the capacity to be independent, autonomous and self-sufficient tends to be more highly valued. Therefore, caring is a practice involving asymmetry, with some getting paid, or not, for caring so others can forget its necessity (de la Bellacasa 2011). Relating this back to the RTS,S partnership, the end of the vaccine trial exposed relationships of dependency and inequality between Northern and Southern partners as these material things became things that trial staff had to continue to care for as they sought new research partnerships.

This chapter focuses on the materiality of the trial, with attention given to how these systems were gained, configured and functioned. But more than this, I explore aspects of medical research not represented in scientific journal articles or research protocols. These include the affect and reflections that informants expressed as the trial wound down and after it ended, and the ways that people provided caring labour, which allow these technical systems to survive, be maintained or shut down. First, I provide an overview of the social science literature about infrastructure. Second, I describe the infrastructure and technology set up for the clinical trial. Third, I examine the way the clinical trial infrastructure was enclaved, or spatially circumscribed, from the wider context in Korogwe. Fourth, I explore how the end of the trial effected trial staff, the material things, research activities and caring practices. Finally, I describe how the material things provided by Northern partners created dependencies for clinical trial staff. This exploration of the material impacts of the trial, the reflections and affect informants expressed, and the care that trial staff provided to these things uncovers social relationships and hierarchies between the people and organizations involved in developing the RTS,S vaccine, and is an avenue to understanding contemporary configurations of transnational medical research.

## Theorizing Infrastructure

There has been a growing interest in infrastructure in anthropology, taken as both an analytical object and metaphor. Infrastructure is conceptually connected to the Enlightenment ideas of the world in movement, in which change and the circulation of people, goods and ideas opened possibilities for progress. Seen through this lens, the provision of infrastructure is intimately tied to the shaping of modern society and the future. For this reason, it is difficult to untangle infrastructures from evolutionary ways of thinking (Larkin 2013; Hetherington 2014).

Infrastructure as an analytical focus can be traced back to critical and Marxist theory. Marx viewed infrastructural technologies as enacting the course of history itself by bringing about change. Through this change, he thought progress could be enacted and through this progress, people could gain freedom. From a Marxist perspective, infrastructures were structures meant to provide stability that allowed for the organization of the market economy and the eventual emergence of higher order processes, which were imagined as civilization, development, progress or freedom. With this process in mind, it explains why infrastructure provokes deep affectual commitments, particularly in resource-poor countries (Larkin 2013; Hetherington 2014).

Science and Technology Studies (STS) has taken the study of infrastructure a bit further. STS researchers have looked at complex data systems, cooperative work environments, transportation systems, and construction of large development projects (Star and Ruhleder 1994; Hughes 1987; Latour 1996; Bijker 2007). These scholars subvert human-centred politics, where objects are excluded and viewed as mere inanimate things. Instead, in their analysis, material objects are central to politics with the capacity to act, translate and mediate.

Anthropologists have contributed to this scholarship with examination of infrastructures such as railways in India (Bear 2007), roads in Peru (Harvey and Knox 2008 and 2012), oil extraction in Equatorial Guinea (Appel 2012), water provision in Mumbai (Anand 2011), and the building of medical research infrastructure (Crane 2013; Geissler 2014; Okwaro and Geissler 2015; Street 2014 and 2016). These scholars demonstrate that infrastructures are more than just material things; their construction and use relate to social and political histories and systems and tell us something about contemporary formations of state and non-state actors. They also reveal the reinforcement and reproduction of political and economic systems in material form.

Several social scientists attempt to define infrastructure as a way to understand it. Bowker and Star (2000) argue that an infrastructure is a black box, an apparatus that is durable but only visible when it breaks down. Infrastructures can be conceived of as a "system of substrates" (Star 1999: 380), which underlie

other systems and include sewers, wires and pipes. Larkin (2013: 329) asserts that infrastructures are "matter that enables the movement of other matter"; they are objects upon which other objects operate. Focusing on medical research in Africa, Geissler (2015b) argues that research sites are conduits for materials, data and people, linking global centres of scientific investigation to surrounding villages. At the same time, they are matter themselves, making infrastructures conceptually difficult to define (Star 1999; Larkin, 2013). Since infrastructures involve many interconnected systems that are part of ever-proliferating networks, it is important to define what will be included under that term (Larkin 2013). In this chapter, I look at specific parts of the infrastructure and technology that supported the testing of the RTS,S vaccine. This includes the physical buildings constructed at the Korogwe Research Centre and trial dispensaries in surrounding villages, as well as the power, communication, virtual and resource networks that were established to conduct the trial.

Looking specifically at the infrastructure built to support medical research in the South, anthropologists (Geissler 2014; Street 2014; Crane 2013) liken these formations to enclaves. Described by anthropologists (Appel 2012; Ferguson 2005) who write about oil and mineral extraction, enclaves are set up in a way that enables companies to disentangle from local social, environmental, legal and political situations of surrounding areas, helping remove responsibility and liability for the surrounding area in which they operate. This practice of disentangling is enabled by "modularity", or the use of self-contained, mobile infrastructures, which operate in the same ways in the world regardless of where they are set up (Appel 2012: 693).

Geissler (2014), examining medical research in Africa, argues that although public health research generally aims to find treatments for diseases largely affecting the poor, public health research stations often operate in similar ways to the pharmaceutical, manufacturing and extraction industries. He refers to medical research centres and field stations as "islands" that when put together becomes an "archipelago" of research hubs that are in a protected enclave, established to exclude. Each centre operates somewhat autonomously from the surrounding setting, protecting and concentrating scientific and clinical capacity and material resources. These facilities support the flows of expertise and funding stemming from centres for technology and science in Europe and North America. They procure resources for their operation and send information collected in the surrounding area to institutes abroad. These research centres have weakened

relationships with nation-states, often operating through para-statal organizations that have both state and corporate traits but rely on state health facilities and state regulation for the recruitment of participants and for health care referral after research concludes. These enclaves are linked through transnational circulations of resources, data and expertise, which 'hop' or crisscross the world and do not necessarily touch upon national structures for research generation and use (Geissler 2012: 200). Existing public health care facilities become sites for research, places to recruit research participants, and hire professionals to carry out research (Geissler 2015a; Crane 2013). This situation mirrors the configuration of the infrastructure constructed to support the RTS,S vaccine trial.

Although the material configuration of infrastructure can help describe how the contemporary scientific production industry operates, infrastructure can also serve as a metaphor. Drawing on a Marxist perspective as described above, social science literature explores how infrastructure is entwined with ideas of progress, possibilities of the future, and of being modern. Due to this entwining, infrastructure is able to mobilize affect, including senses of pride, frustration and desire, feelings that can be profoundly political. Affect can also be evoked with the failure of infrastructure projects when possibilities are foreclosed (Larkin 2013).

I build on this scholarship with my examination of the infrastructure and other material things provided to support the RTS,S vaccine trial in Korogwe. I attend to the ways the infrastructure, buildings and technology were configured and operated, and how people thought about and cared for these things at the end of RTS,S trial. I now turn to a description of the material things that were gifted to researchers in Korogwe to support vaccine trial activities.

#### Making a Place for Science

The Korogwe Research Centre tested RTS,S in a clinical trial from 2009 to 2014. I arrived in 2013, near the end of the trial, thus missing when the vaccine was administered to participants. I was not alone in not observing RTS,S directly; only a small number of the 100 staff members of the trial had seen this vaccine. Nevertheless, the impacts of RTS,S were evident in many places. Clinical spaces had been built to hold, move, administer and test the RTS,S malaria vaccine with a degree of secrecy necessary to maintain the blinding of the trial, so that trial

participants and most trial staff did not know who had received the RTS,S vaccine or an alternative vaccine. People also recalled for me how the trial spaces were once used, situating the vaccine in specific times and places.

A phase two clinical trial for the RTS,S vaccine was carried out using space at the Korogwe District Hospital but more space was needed to conduct the much larger phase 3 trial. Thus, places for scientific research had to be established. Socio-technical assemblages were created—which included the construction of physical infrastructures, transfer of resources, including laboratory equipment and medical supplies—and staff were trained to carry out the testing of the vaccine (Street 2016; Simpson and Sariola 2012).

When I arrived at the Korogwe Research Centre in 2013, Simon, the trial site coordinator, gave me a tour. I noted how starkly the Research Centre stood in contrast to many of the surrounding buildings. The Research Centre was constructed out of concrete that was cleanly whitewashed, with a tin roof that captured rain to supply the building with water. Built in the shape of a square, offices, conference rooms and laboratories were located around the outer periphery, each with barred windows, and there was an inner courtyard of young orange trees in the middle. Concrete benches were positioned around this inner courtyard. The main entrance into the trial site was open and had a concrete sitting area built into the structure of the building for people to socialize. A bulletin board at the entrance had black and white photographs of the building when it was first built. There was also a large sitting area built out of concrete at the back of the building that overlooked the green Usambara Mountain range. The Research Centre was surrounded by lush, verdant farming fields. Cool breezes moved through the trial site and people often met in the hallways to converse or eat lunch together. The Korogwe District Hospital, a low, crumbling, yellow building, was on the other side of the parking lot from the Research Centre.

During the tour, Simon explained that the Korogwe Research Centre had 24-hour electricity supplied by a generator with a backup generator that started automatically whenever the main generator stopped. This meant that the building was not dependent on the unreliable local electricity grid. There was cell phone coverage in the area that aided communication between trial staff and the caregivers of participants. Wireless internet was available at the Research Centre, allowing staff to be linked with the rest of the world. An incinerator was also installed, allowing for the safe disposal of medical waste.



Figure 5: The haematology laboratory.

As he was introducing me to trial staff, Simon showed me the ground floor of the Research Centre, which held the various offices, two conference rooms and two laboratories, which were all air conditioned. The haematology laboratory was situated along most of the front of the trial site and overlooking the parking lot and District Hospital. This laboratory held spaces for analyzing blood samples, preparing blood slides, examining blood slides for malaria with microscopes, filling out paperwork, and archiving blood slides and paperwork. When Simon and I walked into the laboratory, four men dressed in white laboratory coats were filling out paperwork and looked up to introduce themselves and welcome me. Simon and I then looked at the microbiology laboratory situated along one side of the Research Centre. Explaining this room, Simon said, "this laboratory is used to test blood, urine and stool samples from ill patients who are admitted to the District Hospital." Two laboratory technicians were talking to a nurse in a pink uniform who had delivered tissue samples from the District Hospital in an insulated plastic container. Each stopped conversing to introduce themselves and welcome me to the Research Centre. Each of these laboratories had up-to-date equipment to conduct preliminary analysis of tissue samples and prepare samples to be sent abroad for further analysis. Next, Simon showed me the small kitchen and dining area that staff could use to store, prepare and eat food. Two women were conversing in the room and

as I was introduced to them, Simon explained that they cleaned the Research Centre.

Simon and I moved to the basement of the Research Centre, which held the data management offices, archive and pharmacy. The rooms were along a dark hallway lit by florescent lights and there was a metal gate at the entrance. The first office was the pharmacy and stores of pharmaceutical drugs and medical devices were crammed on shelves along the right-hand side of the room, with a long desk in the middle. Simon introduced me to the head pharmacist and junior pharmacist. He explained to me that they were employed to order and dispense drugs, as well as maintain the cold chain for the RTS, S vaccine (this involved keeping the vaccine between the temperatures of 2 and 8 degrees Celsius). Next to the pharmacy, there was a small office for the data manager and an archive situated next to that office. The archive held several shelves filled with binders containing participant information from past and ongoing medical research. Simon explained, "This archive contains records from the phase two RTS,S malaria vaccine, beginning in 2006". Next to the archive was the main data management office. This room had wooden desks along the outer periphery of the room, with a small, barred window facing out the back of the building. Along the walls were shelves holding folders, binders and boxes. One smaller desk was by the door and had a computer and large photocopier and printer on it. When Simon showed me the space, I found six staff members sitting in front of computers with binders full of paper next to them as they entered data into laptop computers. Simon introduced me to the data management staff and explained that the data they were typing into computers was uploaded onto the server and available to GSK in Belgium.

A few days after arriving in Korogwe, I was invited by Brayson, one of the trial doctors, to visit the pediatric ward of the Korogwe District Hospital. This ward served as another area for trial activities and Brayson explained that all the staff members of the pediatric ward, including doctors and nurses, were employed by the trial. As well, the pediatric ward of the hospital received all of its funding for diagnosis and drugs from the RTS,S clinical trial. The electricity from the Korogwe Research Centre did not extend to the hospital so electricity in the pediatric ward regularly cycled on and off. The pediatric ward was an existing resource with its own infrastructure, which was used by the trial to support its activities. In exchange, the trial improved the standard of care provided to all patients admitted to the ward.

Over the weeks that I was in Korogwe, I visited dispensaries built for the trial. Scattered in villages around the Korogwe Research Centre, these dispensaries enabled over 1,500 participants and their caregivers to attend key meetings with trial staff, receive the RTS,S or alternate vaccine, and provide bodily tissues used to monitor the vaccine's efficacy and safety, as well as to access health care near their homes.

Korogwe was chosen to conduct the third phase of the RTS,S clinical trial by a team at MVI. Sharon, a representative of MVI, had been involved in choosing the 11 clinical trial sites across Africa. During an interview in 2015, she reflected on these decisions:

The sites were all selected to balance out the areas that had a lot of impact of malaria and [employees] that had a breadth of experience. We really wanted to balance out the sites. Certainly geography, we wanted east, west. We wanted Francophone sites. [W]e had two [sites] in Tanzania and three in Kenya and two in Ghana to create 'economies of scale' in terms of getting protocols through the national ethics review committees. Seasonality of malaria, places that had pediatricians, [since] not all sites deal with children. There were a whole lot of things that had to be considered and weighted.

Sharon, speaking about capacity building, said, "A lot of the sites didn't have any internet when we started working with them back in 2006.... And one of our sites didn't have electricity!" She expanded on this:

If we get down to the very technical, 8 of our 11 sites had no specific capacity in their laboratories to do microbiology so micro. labs were all developed and so were lab technicians—that's just one piece ... that we needed for the trial ... to make everyone come up to the same standard.

Explaining where the funding for this originated, Sharon said, "[MVI] sponsored a lot of ways for the capacity building, the education, the training and that was in the context of the trial."

The quantity of building at the Korogwe Research Centre differ from that of the other RTS,S clinical trial sites. Although each of the RTS,S vaccine sites required some building and transfer of resources in order to support the vaccine trial, Korogwe had an unusually high level of investment, making Korogwe a special case. The amount of building related to how much infrastructure already existed in the place. Sharon revealed that Korogwe received so much funding "because ... its geographical location; it's pretty remote. ... It really didn't have anything there." Remarking about the Korogwe Research Centre, Sharon said: "That building was built to provide the laboratory, the clinical space, the space to store all the records and the data management. ... [T]hat space became the research centre hub."

Although Korogwe started at a disadvantage in terms of built infrastructure, it had some attractive qualities that spurred investment. Beginning in 2000, researchers have been tracking malaria immunity and mortality in children and pregnant women in the highlands and lowlands of the surrounding area through an ongoing research project named ENRECA, in collaboration with the University of Copenhagen. This data enabled longitudinal tracking of malaria in the area, which allows the impacts of the RTS.S vaccine to be better understood. Also, the Korogwe District Hospital had a pediatric ward which could provide health care to trial participants and there was existing human capacity since a few clinicians, fieldworkers, nurses and laboratory technicians had been trained to carry out previous research studies. Speaking to Joseph, a trial administrator and doctor, one morning in the conference room, he said, "we started with an intervention on intermittent preventive treatment for malaria in infants and there after our site expanded in terms of infrastructure and human resources and then we got the RTS,S phase two and we did it very well. The decision was made that it should go for phase three ... before it could be approved for public use." Beyond these capabilities, it was important that when the trial began in 2009, the lowland areas in Korogwe and Handeni Districts had a sufficient level of malaria transmission that allowed RTS,S to be tested for its capabilities to prevent the disease. Additionally, communities had demonstrated a welcoming attitude towards medical research (despite concerns being raised at the outset of research) and caregivers had enrolled their children in a second phase of the RTS, S trial. There was an expectation that people in the area would be welcoming and willing to enrol their children in the third phase of the trial.

Taking a longer view of history, scientific research has been conducted near the Korogwe Research Centre for over a century. The Amani Research Centre, situated on the Eastern Usambara Mountains just outside of the town of Muheza, was a two-hour drive from Korogwe. German colonizers of East Africa founded Amani in the late 19<sup>th</sup> century. After World War I, the British colonized Tanzania, which was called Tanganyika at the time. Amani became a centre for malaria research with the East African Malaria Institute established there as part of the

imperial aim to eradicate malaria and improve development and colonial welfare in the British colonies of Africa (Geissler and Kelly 2016). In 1979, the Amani Research Centre established a centre for medical research in the nearby town of Tanga, about 100 kilometres from Korogwe (NIMR 2017; Mmbando et al. 2010). Speaking to malaria researchers in Tanzania, they explained that Amani had closed in 2005 due to unstable electricity supply and poor roads leading up the hill to the station. Researchers moved to Tanga town where there were offices and laboratories on the grounds of the Bombo Regional Hospital. This centre was called the National Institute for Medical Research (NIMR) Tanga Research Centre. A lot of the research conducted at this Centre focused on malaria. Joseph said: "when research [was] to be conducted, ... the sponsor looked for local investigators and it happened that we are located in Tanga. So, human resources are available at our site with the relevant expertise to do the trial." Coming from Tanga Research Centre, a couple of researchers were appointed as senior staff members of the RTS,S vaccine trial, making up the small number of permanent staff members.

The Research Centre started at a disadvantage when compared to other RTS,S trial sites across Africa. In order to conduct the third phase of the vaccine trial, Northern partners invested to construct buildings and establish electricity, communication technology and virtual networks, laboratories, offices, and data storage spaces. However, with medical and malaria research spanning over a century in the region, the Korogwe Research Centre was not a completely blank slate as Sharon alluded to above; research capabilities, knowledge about malaria in the region, and health care services already existed and could be built upon, which attracted funders to invest in the area.

Understanding how Korogwe and surrounding areas were perceived as good places for research is important. The dichotomy between attractive and less attractive sites illuminates what counts as 'capacity' when planning for medical research, and who decides this. For this clinical trial, funders decided they were seeking a place that had enough capacity to ensure the trial could commence without starting from scratch. An attractive place for funders was one that had existing medical facilities (including a hospital and rural health care dispensaries), pre-existing data about health outcomes in the area, and a number of people already trained in health care provision, data analysis and other skills and who could then be trained to conduct medical research at an international standard. This place also had malaria transmission, potential trial participants, cell phone coverage, and

roads that connected the Korogwe Research Centre to the study villages and metropolitan areas. The area lacked other facilities to support the trial but too much development may not have been desirable. A lack of development meant that the surrounding area remained rural with a high prevalence of disease. Also, what was constructed could specifically support the RTS,S trial activities.

A number of people I encountered throughout fieldwork argued that the construction of infrastructure through the RTS,S vaccine trial was a positive benefit that not only served the trial but built capacity, with the potential of this capacity to support future medical research and improve health care provision. Yet, as the trial ended, some expressed ambivalence about the trial and observations at the end of the trial uncovered a more complex situation than alluded to in the previous chapter.

## A Medical Research Enclave

Although the Korogwe Research Centre was supporting the work of the RTS,S vaccine trial, it operated in a spatially circumscribed manner similar to enclaves established to support the activities of the extractive industry in Africa, as described above. The Korogwe Research Centre was a field station affiliated with the para-statal organization NIMR. It was run largely independently of the public medical research and health care system and most of its funding stemmed from institutions outside of Tanzania. The Research Centre gained credibility as a generator of evidence about RTS,S in a place where falciparum malaria is prevalent and where the RTS,S vaccine may be available in the future. But in order for the data to be considered valid and comparable across the 11 RTS,S trials sites in Africa, funders required that the data collected about the vaccine be analyzed at a higher standard than what could be carried out in the nearby public hospital laboratory (Street 2014; Simpson and Sariola 2012). Therefore, the Korogwe Research Centre, and the infrastructure built to support the Centre, was necessary to produce credible data.

The buildings and infrastructure of the Korogwe Research Centre was in many ways modular, like that of the extractive industry (Appel 2012). Set up to experiment on people and extract information, blood and other tissue samples, the Research Centre had self-supporting infrastructure and mobile technology that enabled the RTS,S trial. This enclave could be set up in a variety of locations,

wherever industry deemed desirable for experimentation and the collection of data. Resources came in to the Research Centre from abroad and the materials that were extracted flowed out of Tanzania, eventually moving to scientific and technological centres abroad.

The buildings that were constructed at the Korogwe Research Centre provided spaces and infrastructure to support trial activities and protect it from aspects of the surrounding area that could make the findings invalid. The buildings kept out the elements, enabled electricity to flow, and provided the foundation upon which science could operate (Street 2016). This included the construction of places where tissue samples could be collected from trial participants, the establishment of internationally standardized laboratories to carry out preliminary processing of human tissue and data analysis, rooms and shelves to hold archives, and spaces where data could be uploaded onto computers and sent around the world via virtual networks.

The building of two internationally standardised laboratories was key to the operation of the RTS,S clinical trial. These physical spaces held the equipment necessary for conducting analysis of blood and other tissue collected in the course of the clinical trial and preparing tissue samples to be sent abroad for further analysis. It also enabled the protection of the tests conducted from the surrounding places and people that could compromise their validity as scientific specimens. Additionally, the building of laboratories separate from the laboratories in the nearby District Hospital meant there was more control over the analysis and less dependency on public health care infrastructure (Street 2014 and 2016). As well, these laboratories allowed Tanzanian scientists working at the Research Centre to participate as equals in the global scientific field. As Crane (2013: 82) argues, access to "state-of-the-art" facilities is enabled by donors that provide the necessary tools to translate the suffering that people experience in Southern public hospitals and clinics into scientifically legitimate terms accepted in the global North. This situation means that the terms by which global health science operate are determined by the scientific centres in Europe, North America and other resourcerich parts of the world.

The computers in the data management offices had vast amounts of data typed into them and were connected to places outside of Tanzania. These connections required the building of virtual networks and power infrastructure that would work reliably and this capacity was necessary for data collection and the flow

of information (Simpson and Sariola 2012). With Korogwe located six to nine hours away from the big cities of Arusha and Dar es Salaam, internet and electricity were often unreliable. In order to overcome issues with connectivity, GSK paid for a pricy satellite connection to be installed, which did not rely on the internet. As well, the computers in the data management office used energy from generators, which was a more reliable source of energy. These large investments made in setting up a virtual network and functional technological systems allowed the trial to operate but these systems were created so the Research Centre was not reliant on the local power and internet infrastructure.

The Korogwe Research Centre also had security features that helped separate it from the surrounding area and protect the place from theft. Although the Research Centre had been built to be open, with no gates at any of the entrances, a few months before I arrived there had been a robbery with thieves making off with laptops and money found in several offices. After the RTS,S trial ended, bars were installed on all the entrances to make it difficult for non-staff members to enter. Thus, the Research Centre was built, and adapted over time, in ways that both connected and disconnected it from the surrounding area.

The Korogwe Research Centre operated like a resource extraction enclave in particular ways but in other ways, it was distinct from this configuration. Offshore oil extraction is able, through the practice of enclaving and the setting up of modular infrastructures, to produce profit while minimizing or evading contestation from local people (Appel 2012). Medical research is not able to do the same. For medical research, it cannot be completely cut off from the surrounding areas since it must interact with local communities in order to locate bodies for experimentation. These activities mean medical research cannot be easily disentangled from the surrounding area and people, and it cannot operate away from the places where people live.

Ethical considerations arise when research involves humans and ethical considerations are heightened when research is conducted in resource-poor regions. Questions about the value of medical research, of how research activities can improve circumstances for communities, become central to the way that people think about and practice medical research (Kelly and Geissler 2011). With a desire to appear to act in the best interest of communities, companies and organizations involved in medical research claim to make positive impacts on the area they operate through the building of medical research and health care capacity, provision

of health care, and education of locals. However, the outcomes of the RTS,S trial were ambivalent, in part due to how the Research Centre operated as an enclave, separated from the surrounding area.

#### Infrastructure Frozen in Time, Repurposed or Decaying

Up until this point I have analyzed the infrastructure and technology that supported the RTS,S clinical trial when it was in operation. However, when I arrived at the Korogwe Research Centre in 2013, the trial was slowly winding down. At that point, the RTS,S malaria vaccine had been administered to participants and staff were carrying out the last of their data collection. And yet, there were traces of the RTS,S malaria vaccine in parts of the Research Centre and trial dispensaries.

In one room of the haematology laboratory, the vaccines had been kept cold in two large refrigerators before being administered to participants. During my tour of the Korogwe Research Centre when I arrived in 2013, Simon had showed me this room. He pointing to a sign on the door that warned unauthorised people to refrain from entering the room but Simon opened the door and allowed me to peer into the room from the entrance. Simon explained, "This small room is off-limits to everyone but the pharmacists. The RTS, S vaccines were kept in the refrigerators," and Simon pointed to the two large grey appliances crammed into the small room. The two pharmacists who had been tasked with maintaining the vaccine cold chain had monitored the quality of the vaccines and the temperature of the refrigerators regularly. The prohibition on others entering the room remained in effect even after the vaccines had long gone. This barred people from using the room or the refrigerators. This infrastructure was created to support the cold chain and maintain the blinding of the trial. However, this infrastructure was frozen in time and awaiting another drug trial in need of a cold chain. Thus, this infrastructure only served future medical research and experimentation.

I spoke to Caroline, a trial pharmacist, one morning in one of the conference rooms of the Korogwe Research Centre. Caroline explained that the vaccines arrived in Tanzania from Belgium and were held at the Research Centre in the room that was off-limits. When children were being vaccinated with RTS,S, Caroline said, "we had to transport almost 60 to 80 vials", at a time, which were taken to different trial-run dispensaries in the surrounding villages when children were being

vaccinated. Throughout all this movement, the pharmacists maintained the cold chain using boxes made of Styrofoam and cooler packs to transport and keep the vaccines cold. Caroline described how the temperature was monitored: "The temperature device ... provided by GSK, it monitors the temperature, reading the temperature on the inside and you can read it on the outside [of the box]". These devices served as digital thermometers and were checked continually throughout transportation of the vaccines. After the vaccines had been administered each morning, the temperature devices were connected to a computer and information was uploaded and sent to GSK. This was to ensure that the study protocol was followed precisely and the cold chain was maintained, meaning the vaccines were still effective when administered to participants.

I followed the path of RTS,S to one of the trial dispensaries. In the last two months before the end of the trial, everything was in high gear. Each morning, a team of two doctors, two nurses and several fieldworkers visited one of the eight trial dispensaries on rotation to collect blood samples, biometric data and medical histories from the children enrolled in the vaccine trial. Each of the caregivers of the trial participants had received an invitation card a day or two before informing them to take their child to the nearest trial dispensary for the visit. Anywhere from 10 to 40 of the 1,505 participants were invited to come to a dispensary at a time and a new set of participants were invited each morning.

Beginning early in the morning, several trial staff members assembled at the Korogwe Research Centre. I joined them and we drove in three large white vans for over 40 minutes along bumpy orange coloured dirt roads. One of the Styrofoam boxes sat next to me. Although it had once held RTS,S vaccines, that morning it held large binders filled with paper files that recorded information about trial participants. I could imagine what it was like to accompany the RTS,S vaccines to the dispensary as I struggled to keep the box from bouncing around every time we hit a dip in the road. The morning air had not yet warmed to its usually hot afternoon temperatures and with the windows open in the back seat a cool breeze flowed around inside of the truck. We passed sisal plantations, villages and farmland and I spotted people tending crops, bicycling along the side of the road and chatting together under trees. The other trucks traveling with us had extra space and were picking up participants and their caregivers from the surrounding villages as they drove along to the trial dispensary for the visit.

When we arrived at the trial dispensary, Joseph gave me a tour of the building. It was clear what the different rooms were being used for at the time but its layout was built for its original use: to vaccinate children. The large porch was open with corrugated metal roofing overhead to keep out the sun and rain. Joseph said, "Originally, this area was used for participants to wait to be vaccinated. We also kept participants for 30 minutes after they received the vaccine so nurses could monitor their immediate reaction to the vaccine." Walking across the porch we faced three rooms. One room was large, holding two wooden desks and two chairs, a bench for people to sit on as they waited to see a doctor, and shelves filled with children's medicines and medical devices. This space was used for providing health care to children in need or collecting medical histories when the team trial staff visited to collect blood samples. But before, "it was where parents signed consent forms to enter their children into the trial," Joseph explained.

The other room held two smaller rooms with a front room leading into a back room. The front room was small with a well-used metal sink. The back room was used to extract blood from trial participants and fill out paperwork. It had a permanent concrete table built out of the back wall that had been tiled. This table held syringes and gauze to extract blood, along with lollipops to be given to children after their blood was drawn. Joseph pointed to this concrete table and, discussing the vaccination process, said, "One of the nurses prepared the vaccines for administration here." Walking to the front room, he continued: "The nurse would then bring the vaccine, either RTS,S or the alternate, to this room. She would hand it to a second nurse who would vaccinate a child". A pharmacist used a stopwatch to ensure this process was carried out quickly so the vaccines would not overheat. Joseph looked at the window in the room and told me: "During vaccinations, the windows in these rooms were covered with plastic so no one could look in from outside of the dispensary, and the main door to these rooms was kept closed." Joseph explained that these steps blinded the study so no one but the nurses and the pharmacists knew who received RTS,S or the alternate vaccine. This tour uncovered the ways RTS,S travelled and shaped the configuration of the dispensary. This infrastructure, built to support the vaccination process, was later repurposed for other trial activities, including obtaining blood samples from trial participants and providing health care.

As described in chapter 2, several informants perceived this health care infrastructure as a value of the medical research since the dispensaries had the

potential to operate as health care facilities. However, after the RTS,S malaria vaccine trial ended, these spaces were not as functional as expected. A "memorandum of agreement" had been signed between the Tanzanian Ministry of Health and the RTS,S clinical trial partners before the trial began that stated that the ownership of the trial dispensaries would be transferred to the government on the 31<sup>st</sup> of December 2013. Visiting one of the trial dispensaries early one morning a few weeks after the trial had ended, the door to the consultation room was open. I was expecting the room to be empty but instead found three young men writing and reading. Introducing myself to them, they said that they were nursing students studying for exams. They explained that the dispensary provided a light and quiet space to study, an improvement to the dark and busy government dispensary next door.

There was no government-funded doctor, clinic officer or nurse on duty to attend to patients who might come to seek care. The Korogwe Research Centre had received a small amount of funding from MVI and the Tanzanian Ministry of Health to provide care in two dispensaries that had been built for the RTS,S trial. This funding was for a fieldworker to provide a limited level of care and preliminary diagnosis to those in need and help refer them to either a nearby government dispensary or, in case of emergency, the Korogwe District Hospital. Hassan, a trial fieldwork, explained that this service as a way to give trial participants a bit more time to transition into using the government health care system regularly. It was also to maintain good will with community members who might be called on to enrol children in medical research in the future. Hassan was on duty that day but in the hours that I spent at the dispensary, no one sought care at the trial dispensary. The shelves in the consultation room that had once held medicines and medical devices during the trial were empty. Although the space built to support the RTS, S trial had the potential to provide health care, it was now devoid of the objects and substances that could facilitate that care. After my visit to the trial dispensary, I spoke to a clinic officer that had worked for the RTS,S clinical trial. He lamented the loss of medicines in the dispensaries and said, "The Tanzanian government is poor and relies on donor dollars. Once the trial stopped, that was it." This lamentation, a form of affect, expressed how this clinic officer felt in response to both the trial ending and the dependency people had on outside donors to fund medical care.

Several informants claimed that the infrastructure built for the trial, especially the trial dispensaries, would improve health care delivery in the area. With these

newer spaces constructed in nearby villages, it was anticipated that people would access health care and avoid the government dispensaries, which were often in various states of decay. But the buildings alone could not improve health outcomes. These buildings needed trained people and resources—drugs and medical devices—to make health care provision possible. The Tanzanian Ministry of Health struggled to attract health care providers to rural places to work and had trouble even paying them regularly. On a regular basis, necessary drugs and medical devices were out of stock. Despite the perception that these dispensaries were a positive and valuable outcome of the clinical trial, these trial-run dispensaries operated separately from the public health care system and could not easily be linked into it when the trial ended. The dispensaries were essentially litter from global health research, dumped once they were no longer of use. The buildings were gifted to a resource-poor country with no thought for how they might be maintained as health care facilities, burdening people with expensive and operationally useless medical facilities that lacked the necessary resources to make them functional and beneficial to surrounding communities. Thus, the provision of infrastructure did not directly lead to health care system developments and such narratives of success are dubious at best.

Although the utility of the infrastructure built to support RTS,S was of questionable value, it had already begun a slow decline, even before the trial ended. The trial dispensaries, although newer than the government dispensaries nearby, showed their age. At each of the dispensaries, built four years previously, the white paint was yellowing and cracks were showing in the walls. The outer walls had begun crumbling where flooding during the rainy seasons had eroded them. Paint had chipped off walls and the doors and floors of some dispensaries were disintegrating. These features would have been unblemished and new when built but Tanzania's tropical climate wore away at them. Even so, the trial dispensaries stood in contrast to the surrounding setting, with its decaying and severely underfunded public health care system, evinced by the crumbling dispensaries nearby. The government dispensaries next door provided an idea of how the trial dispensaries would look in a few years' time if left unmaintained: yellowed walls, dirty and crumbling floors and walls, cracks in the plaster, broken furniture, mouldering paper work in corners and broken insect screens in windows.

The deterioration was not confined to the trial dispensaries; the Korogwe Research Centre was also in a slow state of decay. Some devices needed for the

smooth running of the RTS,S trial were in disrepair by the time the trial ended. A few weeks before the trial drew to a close, I found Ibrahim, a data manager, trying to repair a printer and photocopy machine. He had taken it apart to see if he could repair a broken part since the activities of the data office relied upon regular printing. "We are so near the end of the trial so they won't replace this with a new one," he explained as his frustration grew. But the care he was trying to provide to the machine was not helping the situation. Eventually, resigned, he gave up trying to fix the machine. This affective expression demonstrated how Ibrahim felt about the loss of capacity at the end of the trial, complicating the narrative that the capacity that was built was static and indisputably positive.

After the trial ended, I went to visit the data management offices in the basement of the Research Centre. I found them in disarray. All the patient files from the archive had been piled on tables and floors, and the desks and tables from the main office had been moved away from the walls. A data manager explained that the archive and main data management office required repair because termites had infested the wood in the basement. The place had been slowly chewed up in the last few years. The Research Centre was not immune to the elements, like every other building in the area. Despite investments in infrastructure and technology, places can be recalcitrant, with the environmental conditions making it difficult to prevent ruination (Sullivan 2012; Street 2014).

Star (1999: 380) argues that when infrastructures are functioning, they are sunk inside and into existing structures and technologies and are thus taken for granted by the user and "by definition invisible". It is only upon infrastructure breaking down that it becomes visible to users. In the everyday work life of staff, I found trial staff took many things for granted when they functioned. People had routines that ensured the smooth running of the clinical trial. These routines involved regular use of the infrastructure and equipment, such as electricity, laptops, printers or blood analysis machines, and these items became commonplace. As well, staff provided care to these things to keep them functioning. This labour went largely unseen by their Northern partners but it was necessary for the conduct of the trial. However, upon technology breaking down, it became glaringly obvious to staff members how remote their location was. Staff could not easily find replacement parts or equipment in the small town of Korogwe and many things had to be shipped to the Korogwe Research Centre from abroad. The breakdown of equipment also indicated how dependent the Research Centre was on their wealthy partners. Care

was not always enough to maintain operability and the buildings and the equipment required regular investments for upkeep. With the government of Tanzania only providing minimal medical research funding (mainly in the form of salaries for permanent staff), funding for maintaining research equipment and infrastructure only came from wealthy organizations abroad. In response to this situation, people expressed a sense of loss, frustration and resignation.

## An Abrupt yet Ambivalent Ending

Several informants discussed how the building of infrastructure and provision of technology through the RTS,S trial improved health care provision and research capacity in and around Korogwe. However, when pressed to discuss the end of the trial, several informants expressed ambivalence about its long-term legacy. Ibrahim spoke about how the laboratory provided testing services to people in the community but then questioned the sustainability of this service: "It helps the community because we're here. But I don't know if after the 31st of December, I don't think it helps."

Wilson, the laboratory technician who had said before the trial ended that the infrastructure built improved care for children in the area, also expressed concern about the sustainability of this care.

A major concern to me is the pediatric ward, the children we have been assisting [there].... [W]hen the project comes to an end, the systems that have been given to the children ... will come to an end.... [B]efore this project started, the death rate in the pediatric ward was very high but now it has reduced tremendously.... So, my worry is, if we won't have someone to sustain this,... it's going to be a major problem.

After the trial ended, Wilson showed me around one of the laboratories. The laboratory was empty and I asked about the loss of staff. Wilson explained that there were few laboratory technicians left at the Research Centre because people were finding new jobs. Very soon there would be no work to do because the substances needed to operate the blood analysis machines, which were central to their job, were running out and cost hundreds of US dollars to replace. The remaining laboratory staff were using supplies left over from the last shipment from their Northern partners as they gradually closed down the laboratory. Wilson did not know if they would receive any more supplies. Without them, staff would not only

lack work but would be unable to continue testing the children that were admitted to the pediatric ward. "All children admitted to Ward 5 should be treated equally to a trial participant but that may end in a few weeks," he said, with resignation in his voice. So, when the trial ended, so too did the testing services, undermining the quality of the health care provided to patients admitted to the pediatric ward. With this, Wilson expressed his disappointment about the situation, over which he had little control.

One morning I was in a car with two researchers working at the Korogwe Research Centre on a longitudinal study about malaria. Driving to the Research Centre to start another day of work, one of the researchers spoke passionately about the end of the RTS,S clinical trial as he steered up the hill, passing homes and fields as we went. He stated:

> It's a shock for people when a trial ends. It's a shock for staff who are out of a job and it's a shock for the community members who expect a certain level of care and services ... After a trial ends, people wonder when another trial will begin. There is a demand within the community for these trials.... I wish the government would take on some of the responsibility of the trial and continue to offer some services.

The expectation was that the state, not global health partnerships or a research study, should be the long-term provider and conduit of health care. But the government lacked the funds to sustain the services provided by the RTS,S clinical trial. With resources, including drugs, health care staff, and the substances necessary to operate diagnostic testing machines, withdrawn after the vaccine trial, high quality health care could no longer be provided in the hospital or the dispensaries.

As well, with the clinical trial concluded, much of the human capacity built to carry out the trial was lost, with a majority of staff becoming unemployed. Those who were well-educated and able to relocate felt confident about their abilities to find work and some planned to move to major Tanzanian cities and work for private clinics or laboratories. Crane (2013: 138) refers to this as "internal brain drain", whereby the public health care sector is abandoned for higher salaries from foreign NGOs and research, which does not always lead to improvements for health care delivery in impoverished places. But for those who originated in Korogwe and were less educated, they expressed distress that they did not know what to do once the trial ended. With no large-scale trial on the horizon, staff either did not remain in the

resource-poor area where the trial was conducted, or for those who remained, they saw an end to their employment and incomes. Although medical research and health care infrastructure was built, it is questionable how sustainable this development is if few people remain in Korogwe to make use of it.

Despite several members of the trial staff expressing frustration and resignation about the limitations of capacity building through the trial, Tom, a British malaria researcher at a West African RTS,S trial site, reflected on the perceived lack of investment into research capacity building:

I think one thing that the Africans have felt is that there haven't been enough of an investment research capacity development.... And that is where some of the conflict has been.... But the purpose has been to get this vaccine registered and that's what we should be doing, everything should be around that.... [T]here has ... been a wish for some opportunities to do some Master's courses or learn some small theoretical things and I think they were a bit frustrated ... that there wasn't some money for that..... [S]omeone else should have come in with that, to build on the sort of structure...

By saying that someone else should have made investments into capacity building absolves GSK and MVI of their responsibility to African researchers and research centres. But those I spoke to at GSK and MVI explained that they had invested quite a bit and it was no longer their responsibility to continue with that investment after the trial ended. However, for trial staff, on the other hand, they experienced the ending of the trial very differently to people at GSK and MVI as they grappled with unemployment and a limited health care system.

Street's (2014) findings resonate with my own. She conducted research at a government-run hospital in Papua New Guinea and explored the impacts science can have on a place. Street found that when researchers propose to conduct scientific research in the hospital, they must profess to be directly investing in public health care capacities in order to gain ethical clearance by government research gatekeepers and international research funders. However, when examining the impacts of a clinical trial for a malaria medication, she found that research capacities were built separate from the hospital and improvements were slated for some unspecified time in the future. Researchers had only built enough capacity to conduct their research but not to become health care providers or improve the provision of health care in the hospital. Similarly, GSK and MVI did not continue to be health care providers in Tanzania after the trial ended.

When the trial ended, this evoked a range of feelings from trial staff. Many expressed happiness about the investments made in Korogwe and surrounding areas, as discussed in chapter 2. But some questioned the long-term legacy of the trial when the clinical trial was both temporally and spatially circumscribed from the wider community and health care system. As well, as the potentials of the trial were foreclosed, some staff expressed concern, frustration and resignation as things broke, ended or were not sustained. Although some expectations were met for capacity building, the abrupt end of the trial exposed the limited obligations and commitment of transnational companies and organisations to places where research was conducted (Geissler 2015b).

## **Care and Dependency**

At the end of the trial, it was uncertain if the Korogwe Research Centre would attract another research project. Sharon said,

We were the sole funder of [this site].... [F]or years this was the contract that kept them operating. ... A hundred people,... fieldworkers, laboratory people, clinical staff, clinical officers.... What was going to happen to all these people? There weren't a lot of opportunities to just pick up another project.

Some RTS,S trial sites in Africa had core support from large organizations like the United States Centres for Disease Control (CDC) or multiple large and ongoing research projects. However, Tom explained that "some ... African [research] centres which don't have strong core support ... are ... very dependent on ... big trials, for supporting infrastructure, paying the electricity, and so on."

The Korogwe Research Centre was one of the centres that lacked core support. Attempts had been made to attract large research projects to the Research Centre. Sharon explained,

> Obviously after five or six ... years of developing capacity, one of the things we consciously did is that we began to think about the transition of the sites from this big project to how they're going to become sites for other research.... One of the things that MVI did was sponsor a workshop with the investigators about ancillary studies and we did a whole session on grant writing. We ... have reached out to the other PDP's [Public Development Partnerships] to try to drum up business ... for these trial sites, to advocate for

them.... It's a way for ... the investigators and the teams to continue the ability to conduct rigorous research in the field.

MVI also posted an advertisement for the Korogwe Research Centre on an Oxford-based research site finder. With this resource, a company or organization that wishes to carry out medical research can search for research sites online and find hundreds of sites around the world. Thus, the potential was there for Korogwe to continue medical research. Sharon continued,

[W]hat we have been trying to do centrally here is to tout the good reputation [of RTS,S trial sites]. I personally get calls all the time, 'Oh, have you ever worked with this site'. So, again I think there is a way to sustain some of the momentum in the sites. That is something that we are very cognizant of and we did our level best to prepare for the transition but it's challenging.... [A]t our 11 sites, some have been in business for 20 or so years and they have a diverse funding portfolio of projects, or they work on other diseases and have contacts with other drug companies to do other malaria drug studies. And then some of them were really just conducting this one vaccine trial.

Administrators at the Research Centre attempted to draw researchers to conduct projects there. One day before the end of the phase three trial, a group of around 20 research students from Denmark visited the Korogwe Research Centre. They were given a tour and served lunch. Administrators hoped that these students would consider conducting a research project at the Research Centre and help to bring in research funding. A few weeks later, a faculty member from Denmark arrived at the trial site to establish a research project with a Tanzanian researcher affiliated with NIMR. These researchers planned to track the health of children from birth to understand how diet during gestation can affect diabetes rates. The Research Centre would serve as the hub for their activities and they would make use of the laboratories and offices to support their research. However, this study was small-scale and would only involve two researchers, one Tanzanian and one Danish, and would not impact the Research Centre in a significant way since the samples obtained from research participants would be analyzed at the University of Copenhagen.

It proved difficult to attract another large-scale research project to the Research Centre. Joseph explained why another research project had not found to replace the RTS,S trial when it came to an end: "With respect to research, we are trying to diversify. Not only do malaria research but in other areas, other diseases. ... [I]t's unfortunate that we were caught before we were adequately prepared to diversify our research". I spoke to Erick, a fieldworker, about this issue before the trial ended. He remarked: "We always cry for another study. I don't know if at the end of December if there is any promising answer but we are eager to see that these facilities are active all the time. The problem is getting other projects that can use these facilities".

Despite being unable to draw another large-scale study to the Korogwe Research Centre when the RTS,S trial ended, this site remained attractive as a research site because it could host medical research in a rural area and be modified to support a variety of research studies. This relates to Appel's (2012) term, "modularity". As Appel argues, the infrastructure used for oil extraction is mobile, self-contained and compliant and can be set up in many places around the world to enable the oil industry to disentangle from surrounding areas where they work. Similarly, the Research Centre comprised of infrastructure that was self-contained and could be assembled in different settings. However, unlike Appel's meaning of modularity, the laboratory equipment at the Research Centre had a particular function: to carry out analysis of blood and tissue samples before they degraded with further analysis conducted in more equipped laboratories abroad. If a different kind of research was to be conducted in Korogwe, the laboratory equipment would need to be interchanged for other equipment. With further inputs of resources from wealthy research partners, new laboratory equipment could be procured. In order to diversify research activities, researchers in Korogwe would need to negotiate for more equipment and investments into the infrastructure and technology, putting researchers in a position of dependency in relation to incoming organizations (cf. Okwaro and Geissler 2015).

Although many considered the RTS,S clinical trial—through the establishment of scientific infrastructure and provision of technology—had benefited Tanzania, in actuality the benefits were largely unsustainable. Okwaro and Geissler (2015) have written about medical research infrastructure in East Africa:

Developing infrastructure is ... like joining an elite club of institutions that can continuously conduct research. The converse scenario is what one observes in non-collaborating research departments, where institutions and scientists lack infrastructure and are therefore unable to compete for collaborators, resulting in a downward spiral of research inactivity and decay. (14)

Medical research funding in low-income countries is often unavailable from governments so researchers must collaborate with organizations willing to fund research activities. Research can be short-lived and when studies end, so too does the funding, resources and support necessary for capacity building. Therefore, research centres in resource-poor places are highly dependent on regular investments from wealthy donors to maintain and expand infrastructure and technology. Securing funding for various medical research activities—including the building of research sites and obtaining laboratory equipment from outside institutions—is key to the success of research centres. Research centres that do not have support from outside institutions for building infrastructure are unable to attract research and thus experience increasing inactivity, decline and decay. Research centres that have support from institutions abroad for the building and maintenance of infrastructure and laboratories are able to attract research projects and maintain active research centres (Okwaro and Geissler 2015). However, in this situation, researchers are dependent on relationships with wealthy institutions to grow and sustain capacity, meaning that capacity building is not always stable. The time-bounded nature of research projects means that the impact of research can be short-lived and impermanent, unable to directly lead to sustainable change. As well, this situation reinforces unequal relationships between wealthy donors in the North and researchers in the South, despite these relationships being portrayed as partnerships (Geissler 2015b; Okwaro and Geissler 2015).

Returning to the decaying technology at the Korogwe Research Centre, the breakdown of the printer in the data management office occurred before the RTS,S phase three clinical trial ended. At this time it was uncertain if the Research Centre would continue researching RTS,S. After the phase three trial ended, GSK informed administrators of the Research Centre that there was a possibility they would secure a contract to conduct the fourth phase of the RTS,S trial. This fourth phase would be a pharmacovigilant study that would set a quantitative standard for the level of disease in the area, which would be used as a comparison for when the RTS,S vaccine was administered at a later time. Only then were funds provided to purchase a new printer and repair the damage termites had made in the Research Centre data management office. As well, this potential for further research was the reason minimal health care was provided at two of the trial dispensaries.

This situation reveals how dependent research centres in low-income countries are on wealthy institutions and organizations to grow and sustain this

capacity. Research centres must provide things of interest—be it a location, willing communities, or diseases of interest—to international capital. When circumstances change, these places are disconnected, leading to abandoned sites and decay (Harvey and Knox 2008; Okwaro and Geissler 2015; Geissler 2012). Thus, the Korogwe Research Centre experienced times of decay and repair in relation to how disconnected or connected it was to outside donors and partners. However, when the opportunity arises, the Korogwe Research Centre has the potential to be reanimated but this requires funders who desire to do more research in the area for investments in the Research Centre to resume (Geissler 2015b; Okwaro and Geissler 2015; Crane 2013).

MVI and GSK invested in the Korogwe Research Centre, constructing buildings, creating electrical, communication and virtual networks, and setting up laboratories and data management spaces. Northern partners expressed a sense of satisfaction with their provision of these gifts and many informants claimed that the vaccine trial had value beyond the development of a malaria vaccine through the building of capacity, which was thought to improve health care provision and enable future medical research. However, when the RTS,S trial ended, the ambivalent impacts of these material things became obvious. Trial staff saw the potential for progress through infrastructure and technology foreclosed at this time. This evoked affect, including frustration, concern and resignation. The clinical trial was enclaved, small-scale and time-limited. The impacts were of limited value or helped support the aims of Northern partners and global capital more than researchers and people in surrounding communities, fitting with the ideas about gift giving described by Malinowski (2014 [1922]) and Mauss (2011 [1925]). The infrastructure constructed to maintain the cold chain was frozen in time and the trial dispensaries were constructed to administer the vaccine and provide health care to trial participants but were then left for the government to figure out how to use, with little funding provided to staff the dispensaries or supply drugs. Also, the Korogwe Research Centre and the technology inside was decaying, with the rain, sun, termites and regular use wearing away at the once bright and new building and functional equipment. Ongoing care and investment were necessary to maintain the functionality of the Research Centre. This made researchers in Korogwe highly

dependent on establishing partnerships with wealthy institutions. These findings expose the historically-shaped hierarchies between North and South that continue to shape current formations of global health research, as well as the limitations of contemporary global health partnerships in bringing about broader and longer-term changes in places of need.

My findings also suggest a new understanding of global health partnerships. Northern partners largely disengaged from the partnership once the trial concluded but for trial staff in Tanzania, they continued to care for the buildings, technology and infrastructure by repairing them and maintain their operability as best they could as they sought other research partnerships. Relating these findings back to theoretical ways of understanding infrastructure, trial staff continued to value the material things because they viewed them not only as gifts but as an avenue towards change, progress and development. The caring labour that trial staff provided to the material things was largely unseen by Northern partners who, after the end of the trial, relinquished their obligations to the material things they had given Tanzanian researchers. In this way, staff in Korogwe experienced the partnership more fully and in an ongoing way even after the trial ended since they had to contend with and care for the materials given to them by their partners. My findings suggest that partnership is not only a rhetoric that disguises inequalities and hierarchies. By focussing on the materiality of the RTS,S clinical trial, I demonstrate how the concept of partnership is given meaning as people joined together to care for and use these materials to develop a vaccine. But more than that, partnership is an idea that needs only to be fully believed and supported by one side to be effective in mobilizing people's involvement. In the case of the RTS, S vaccine trial, Northern partners could step away from the partnership. However, trial staff in Tanzania derived meaning and motivation from the partnership, and expended labour, care and affect in order to feel fully involved and to make the partnership come to life.

# Chapter 4: The Boundaries of Care: Material Exchange and Health Care Provision at the End of the RTS,S Clinical Trial

## Introduction

Although the literature is rife with descriptions of how health care systems in many Sub-Saharan African countries are struggling, the situation in Korogwe diverged slightly from those descriptions. When it was ongoing, the RTS,S malaria vaccine clinical trial received funding from GlaxoSmithKline (GSK) and the Malaria Vaccine Initiative (MVI) to provide health care to children in and around the town of Korogwe. The trial constructed health care infrastructure, improved access to resources like pharmaceutical drugs and medical devices, and directly provided material resources and labour to support public health care facilities.

The provision of health care was an ongoing activity for trial staff throughout the RTS,S trial and commanded a significant amount of time, labour, care and resources. These activities also included many exchanges. I described a large exchange in chapter 3, whereby staff provided their labour and time in return for employment and material things—including buildings and technology—from their Northern partners. But throughout the trial, there were many exchanges between trial staff and public health care staff, and trial staff and community members. The public health care system allowed the trial to use the pediatric ward of the Korogwe District Hospital and facilitating enrolment of participants into the trial, as material objects, information, labour, time, and blood samples were exchanged back and forth between people. These exchanges impacted social relationships and the very conception of health care.

The nature of exchange has occupied a considerable amount of thought, debate and discussion in anthropology, beginning with Mauss (1990 [1925]). This topic has particularly engaged anthropologists studying Melanesia, where ideas about personhood, objects and exchange often differ from Western conceptions (Strathern 1988; Knauft 1999; West 2006). Strathern argues that for some communities in Melanesia, objects and people come into being through giving and exchange, and people become social actors through their exchange, possession and use of objects (Strathern 1988). A majority of Melanesianist anthropology focuses on the movement of people and objects in relation to the formation of social selves and social relations. However, West (2006) expanded this theory after researching a conservation initiative involving the Gimi people of Papua New Guinea and a conservation non-governmental organization (NGO). She found that services and labour, as actions, can also be viewed in relation to exchange and the reproduction of social relationships. What can be derived from these examples is that objects, people and social relationships can come into being through the exchange of objects, labour and services. I apply these ideas about exchange to the RTS,S vaccine trial to explore how the public and privately-funded health care services interacted and came into being through exchange.

In the town of Korogwe, the ability to access private health care was limited and the public health care system was largely the only system available. However, during the trial, excellent health care was provided at an internationally standardized level in order to minimize the possibility of harm to trial participants. Trial staff provided this care to trial participants and neighbouring children, whether they were part of the vaccine trial or not. The health care provided through the trial operated in parallel and, in some cases, within the public health care system. This situation did not blur distinctions between public and private health care. Instead, I argue that the many exchanges between the two services exposed the differences between the two, and through exchange, the public health care system came into being, with people coming to see and understand this system and its limitations.

Additionally, after the trial ended, trial staff largely ceased to provide care. From the perspective of people at GSK and MVI, ending health care provision was necessary because their mandate was to test a malaria vaccine and they could only invest in this service as the trial was ongoing. Moreover, they oriented themselves towards the future when thinking about their impacts on Africa, as the development of the RTS,S vaccine has the potential to lift all boats, so to speak, once provided. However, for many trial staff, the ending of health care provision was problematic. Due to the trial, staff had gained a normative view of health care, making it obvious what the public health care system should be like, and where it could go in the future. There was expression of loss and a sense of duty to continue to provide care. As well, this ending evoked a "medical imaginary", to borrow Wendland's (2012b) term, with some trial staff expressing a political demand for a better public medical system in Tanzania. Thus, the RTS,S trial left more than material things behind; it left behind ideas of how the Tanzanian public health care system should and could operate.

In this chapter, I first provide background on anthropological literature about health care and medical research. Second, I describe the rural dispensaries operated by the government in communities around Korogwe and highlight how health care providers navigated the public health care system. Third, I explore the ways that RTS,S trial staff provided health care, trace the movement of material objects, and examine exchanges of labour, care, time and resources between the public and privately-funded health care services. Finally, I focus on the end of the RTS,S clinical trial and how a private enterprise helped trial staff to re-think how to provide public health care. Overall, my findings uncover how boundaries and differences were created and reinforced through exchange and closures.

## Health Care and Medical Research

Anthropologists (Fairhead, Leach and Small 2006; Leach and Fairhead 2011; Geissler 2013, 2014 and 2015b; Geissler et al. 2008; Crane 2013; Whyte 2011; Nguyen 2015; Marcis 2015; Kelly et al. 2010; Kelly 2011) have explored medical research studies conducted in a variety of African countries and each found health care was provided in the research studies they examined. However, health care has not always been provided during the conduct of medical research in Africa. As described in the introduction of this thesis, the 1990s saw a dramatic rise of research carried out in resource-poor settings and ethical codes were revised to protect vulnerable people. But Petryna (2005 and 2009) highlights that adherence to ethical codes can be dependent on context. In some places, ethical codes may only be loosely interpreted and followed. For example, in 1994, an HIV medication was tested in Africa to see if it halted transmission of the virus during child birth. Researchers followed ethical codes, which stated that "equivalent medication" could be given to those in one group of the randomized control trial. This group received a placebo, which was essentially no treatment, as the other half of the participants received the experimental treatment. This was cheaper than having to provide all research participants with adequate care and drugs. This practice led to an outcry but it was not breaking any ethical codes. That researchers could provide little to no

treatment in places with weak health care systems indicates that the application of ethical codes can vary.

Despite this variable interpretation and application of ethical codes, many research studies follow the Declaration of Helsinki of the World Health Organization (WHO) and other ethical codes that specify that research participants not receiving the experimental drug or vaccine should be given the best available form of prevention or treatment, not a placebo. As well, these codes stipulate that all research participants must receive the best treatment currently available and medical research conducted in resource-poor settings must include the provision of care that is at least equivalent to that of the sponsoring country. If research participants become ill, treatment must to be provided so they did not suffer unduly (Angell 1997; Petryna 2009).

When health care is provided over the course of medical research, this can impact health care services in local contexts. Health care in many African countries has increasingly been privatized and defunded over the last several decades and governments have established transnational partnerships with NGOs, charities, foreign governments, and industry to provide partial, fragmented and emergency-focused care. This situation means that people, a majority of whom continue to depend on decaying public health care facilities, must navigate a fractured health care landscape, accessing health care where possible. In some places, medical research provides health care (Geissler 2012 and 2014). This has brought about the "experimental subject" (Nguyen 2009), a common figure found in impoverished settings in the Global South as people are given the choice of participating in research and receiving quality care or refusing to participate and not getting access to health care (Marcis 2015).

Contemporary discussions about medical research tends to frame it as distinct from public health care. However, this distinction may be less than clear in some contexts. Whyte (2011) explores how research and health care can overlap, blurring distinctions between the two service providers. Examining medical research in rural Uganda, she finds that it can supplement the poorly funded public system and from the perspective of those being researched, medical research was often not clearly distinguished from health services. As well, Whyte found that people showed little concern that the research collected knowledge; the provision of health care was more significant to them.

Exploring people's perceptions and use of health care provided through research, Leach and Fairhead (2011) found that in The Gambia many people became experimental subjects. This helped them gain access to health care through clinical trials and medical studies conducted by a British Medical Research Council (MRC)-funded field station. The authors found the distinction between medical research and health care was less than clear in contexts where research institutions operate over long periods of time. For the MRC field station in The Gambia, it had been in operation for over 50 years, providing health care from within a government health care. Through its lengthy engagement, the field station became part of the health care landscape and people living in the area viewed it largely as one amongst a multitude of health care providers, rather than simply a research station.

Although the MRC field station in The Gambia has hosted medical research for decades, not every field station or research centre accommodating medical research can sustain research activities and the medical care that often accompanies it. In some cases, health care and its attendant resources are only offered for as long as the research is ongoing and funding is flowing. Geissler (2014), having conducted research at a public health scientific research station in East Africa, found that exceptional medical services were provided to those who participated in medical research. At this research station, enclosed treatment spaces functioned in parallel to the public health care system. When researchers were able to draw in funding to support research, there were periods of heightened activity along with the provision of health care. However, there were time limitations to this funding, leading to periods when people were cut off from accessing resources. This meant that medical research was not a sustainable source of medical care.

Crane (2013) writes about global health partnerships and medical research in Uganda, finding that foreign-funded research can provide a level of care unavailable from public health care facilities. She explores the growth of a HIV/AIDS (human immunodeficiency virus/acquired immunodeficiency syndrome) clinic in Uganda that began receiving funding from international donors in 2005. Staff, infrastructure and patient numbers grew as thousands received treatment for HIV, and US-based researchers established partnerships and became involved in conducting research in the clinic. This situation obscured the division between humanitarian and scientific activity. However, this clinic was enclaved from other

health care facilities and there was an increasing disparity between the clinic and government-funded hospital wards that lacked even basic supplies. This meant that those not suffering from HIV/AIDS could not reliably obtain treatment. As well, although thousands received treatment at this clinic, services ceased when foreign grants did not materialize. Here too, medical research did not offer comprehensive health care to those in need or sustainably strengthen the health care system in Uganda.

The examples above are similar to the RTS,S clinical trial in Korogwe, Tanzania. During the trial, the RTS,S clinical trial operated within and alongside the Tanzanian public health care system. But, unlike examples in the literature where the boundaries between medical research and public health care were blurred, the exchanges between the public and private helped maintain distinctions between the two. Additionally, much like what Crane (2013) and Geissler (2014) found with their research, when the RTS,S trial came to a close, it did not sustain access to health care or resources because it had a time-limited mandate to test a new vaccine. Thus, the health care provided through this clinical trial was circumscribed, bounded in space and time. This had particular effects on how people came to see and understand the public health care system in Korogwe. Below, I provide a description of the public health care facilities I visited and health care providers I met during my time in Korogwe and Handeni Districts.

## The Public Health Care System

In the Districts of Korogwe and Handeni, a leading reason people seek out medical care—whether public or private, naturalistic or biomedical, formal or informal—is due to malaria. This disease is endemic to the area and most prevalent at lower-altitudes, especially during the rainy seasons. As well, malaria disproportionately affects not only children and pregnant women but those in poverty (Kelly and Beisel 2011; Desowitz 2002; Mahendi et al. 2014; Mmbando et al. 2010). Grace, a laboratory technician, spoke to this issue when I interviewed her at the Korogwe Research Centre one afternoon in her office. She said, "What they say is that malaria is equivalent to poverty, poverty is equivalent to malaria.... Once you have malaria, you can't come to work, you can't produce, you can't do anything.... [E]specially when you are poor, [malaria] is even worse." Tanzania has widespread

poverty (WHO 2009) and poverty can impact health in a variety of ways. For example, people in poverty often lack mosquito-proof housing, something that I observed when I visited the homes of a few trial participants. Lacking housing that protects from mosquitoes can lead to a greater chance of contracting malaria and thus a greater need for health care provision.

Different kinds of health care providers existed in Korogwe and Handeni Districts. People sought care through private pharmacies, traditional healers, or, if able, private health care facilities in larger metropolises. However, there was little access to private health care services in the area and the public health care system was largely the only health care system available. Therefore, a majority of people who sought out allopathic medicine attended a public dispensary or hospital in the area.

Although many people depended on the public health care system to obtain care and malaria medications, this system was severely underfunded. In order to get a sense of the health care services, I visited the Korogwe District Hospital and several village dispensaries that were located near trial dispensaries. One morning at a RTS,S trial dispensary, I spent some time with Fredy, the clinic officer on duty. He suggested we visit the government dispensary situated a few feet away. The government dispensary was constructed of concrete, cracked and eroded, with a tin roof. Windows were dark with dust that had been kicked up from the highway in front of the facility, and window screens were rusted and broken. Entering the dark front room of the dispensary, patients were lined up to sign in with a nurse to see a health care provider. Fredy introduced me to this nurse. She wore a bright blue uniform and sat at a wooden desk with a ledger in front of her. Fredy explained to the nurse that I was doing research and wanted to look around the dispensary. The nurse smiled, nodded and said, "Karibu! [welcome]". Fredy led me past the people lined-up and we walked into the room at the back of the dispensary where there were several women, some with infants in their laps, sitting on wooden benches around the outer periphery of the room. This room had a big, barred window and a door that led outside, which let in natural light. A few public health posters in Swahili were hung on the walls. A wooden desk and chair, along with a baby weighing station, sat in the middle of the room.

Fredy knocked on the first door to the right and a man, wearing a white doctor's coat and looking to be in his mid-20s, opened it. He introduced himself as Jonas and said he was the only doctor for the dispensary. Fredy introduced me and

told Jonas that I was conducting research about the RTS,S vaccine trial and wanted to look around the dispensary. Jonas welcomed me and waved us into the room. I saw that the room was cramped and dark. A woman was lying on a bed covered with a plastic sheet and a cloth, wearing a yellow and black patterned khanga cloth wrapped around her, her back to us. Jonas explained that she was in labour. When the woman saw us, she made an effort to cover herself more but with a wince of pain she returned to having her arm over her face to keep out the sliver of light coming in between the window shutters next to the bed. The room contained three rusted beds, intravenous bag holders and a large wooden desk. The top of the desk held log books, papers and medical supplies, and the walls and floors of the room were discoloured from years of use. On the bed next to the woman in labour, there were metal surgical instruments, ready for use. Once Fredy and I entered the room, Jonas asked that I close the door "to protect the confidentiality of my patient," he explained, since the women sitting outside on the room would be able to peer in. Jonas explained that the woman on the bed had gone into labour in the village that morning and was past due to deliver her baby. She had been trying to make it to the dispensary from her village but was in a lot of pain so dispensary staff picked her up in a nurses' car.

Jonas said that he had been a doctor for three months and loved the job since he felt he was helping people. He liked working aside the other members of staff, including two assistant nurses and a cleaner. But then Jonas described the challenges he faced at that dispensary, with regular drug stock-outs and insufficient supplies. Jonas pointed to the woman in labour and said, "The women are told on the radio and on the television that they can give birth in a dispensary or hospital for free but when they come they find they must pay for the sheet on the bed and medications. They have to reach into their own pockets." He explained he felt torn about whether he should help patients when he is trying to scrape by as well. "You know, we are still waiting for the monthly pay-cheque for our salary, even though it's a few weeks into the month now."

As Jonas was talking, there was a knock on the door and he opened it. An older woman handed Jonas a black plastic bag and he explained to us that the older woman was a relative of the woman in labour. Jonas then pointing to the plastic bag and said, "See, I have to get my patients to buy supplies. They even have to get their own Oxycodone—their own pain medication." As he pulled two plastic bottles of clear liquid out of the plastic bag, he continued: "And here are some IV fluids,

because every delivering woman needs these." He shook his head and looked in despair. Jonas told us about how supplies were lacking at the dispensary and how he submitted orders for supplies but repeatedly found he was not given what he asked for. "I don't know why they do this, maybe they don't have enough money? But every time I find I do not get exactly what I ordered, always less."

After the RTS, S trial ended, I returned to this dispensary one afternoon. I found the dispensary quiet and remembered that Hassan, a trial fieldworker, had said that the heavy rain during the last two days meant people were in the fields planting crops. Walking to the back room, I found it empty except for Jonas sitting on a wooden bench usually reserved for patients waiting to see a health care provider. Jonas was wearing his white doctor's coat and sewing up a rubber device. I greeted him and he welcomed me to sit with him as he attempted to sew up an aspirator with a needle and string. As I watched, I could see that his attempts were not working and he gave up in frustration. Pointing to the device, he said, "I use this to help babies breathe if their airways are blocked after they are born. Without it I have no way of clearing the airway and babies will die. I will order a new one but I know it won't come for three or four months. In the meantime, what will I do?" Jonas asked. "I'm also out of S-P [sulfadoxine-pyrimethamine] to give to pregnant women to prevent malaria." Although there were trained staff at this dispensary, there was a lack of resources to support health care, which evoked frustration, helplessness and resignation.

As Jonas explained, he placed orders for the drugs and medical devices he used in his practice. His orders were filled by the Medical Stores Department (MSD), an independent, para-statal organization established by the Tanzanian Ministry of Health in 1993. Supplying health care facilities throughout the country (Gerrets 2015), the government health care providers that I spoke to had reservations about its ability to adequately serve the country. With regular stock-outs of drugs experienced across the country, many health care providers I encountered felt resignation about their ability to provide quality care to their patients. Although care for children under the age of five was technically free of charge in Tanzania, if the drugs were unavailable in public health care facilities, they had to be paid for out-of-pocket at a private pharmacy. In Dar es Salaam, before commencing research in Korogwe, I spoke to two representatives at John Snow International (JSI). This organization was tasked with improving the MSD's drug provision system through a grant from The US President's Malaria Initiative (PMI).

These representatives of JSI attributed the poor delivery of drugs to technical faults in the system and explained that JSI was in the midst of digitizing the system so health care providers could request and track drugs and supplies using computers. However, when I was in Korogwe, this system was not yet in place.

I visited other government dispensaries as the RTS,S trial was coming to a close. One morning at a trial dispensary in the lowlands of Korogwe District, I was speaking to Juma, a clinic officer working for the RTS,S clinical trial. He explained that he helped out at the government dispensary nearby when things were busy there. Juma said he was happy to help as he knew how overworked staff could be, while he, on the other hand, had few patients to attend to as the trial wound down. Because he shared his time and labour, Juma had come to befriend the staff at the government dispensary and said that he would be pleased to introduce me to them.

Juma took me to an examination room in the government dispensary, which was a few metres away from the trial dispensary. There, Juma introduced me to a clinic officer named Godfrey, who was middle-aged and wearing a white doctor's coat. Juma explained my research to Godfrey and he said he would gladly show me around the government dispensary. We first went to the maternal and infant health building. There, several women and children sat on wooden benches or the floor. An infant weighing station was in the middle of the room with nurses placing babies in slings and recording their weight. There were examination rooms off of this main room and Juma and Godfrey showed me to the room nearest the entrance. A nurse in white dress was speaking to a woman with an infant swaddled and held to her chest with a patterned *khanga* cloth. Malaria medications and other drugs were in the cabinet near the door of the room and I spotted a voucher for insecticide-treated mosquito nets on the desk. This voucher allowed pregnant women and children to receive a bed net for 500 Tanzanian shillings (equivalent to about US\$0.30). Thanking the nurse and woman for letting us view the room, we moved on to the next building.

Reserved for labour and birth, the next room was large and held two beds. Cleaner and brighter than the government dispensary that I visited before, the two barred windows in the room had clean glass that let in the morning light. The walls and floor were stained with use and there was no running water; water was held in large plastic buckets on the floor. On the walls were instructions for helping women in labour. The clinic officer working for the government said, "Sometimes women come at night and there is no electricity so we must deliver the babies by kerosene

lamp." He continued: "Some doctors even refuse to treat patients at night." He explained that bad pay was the reason some were selective about what care they were willing to provide to patients. I asked how many women gave birth at the hospital and the clinic officer said, "Around 40-50%, the rest stay at home."

Moving onto the pharmacy, located in another building of the dispensary, I saw that it was stocked with a supply of malaria medications. The clinic officer explained, "We ran out of mRDTs [Rapid Diagnostic Tests for malaria] a month ago so we must treat malaria clinically by looking at the symptoms people present". I opined that malaria can look like other infections and the two clinic officers looked apologetic. Juma explained, "There is nothing they can do about this, they have to make do with what they are given."

I visited several other government dispensaries over the two months that I was in Korogwe. Overall, the public health care providers that I spoke to described the public health care system as underfunded, leading to overworked and underpaid staff. Medical devices were in disrepair and stock outs of drugs were a regularly occurrence. The government dispensaries I visited were in disrepair with cracking concrete, rusting metal roofs and bed frames, with paperwork piled up and mouldering in corners. Electricity was often unavailable, as were laboratories, leading to a reliance on rapid diagnostic tests for diagnosing malaria and HIV, when available.

People living in surrounding villages had to travel to public health care facilities either on foot, pay someone to drive them on a motorbike, or, if they lived along a main road, take a *dala dala* [mini-bus]. One hot afternoon outside of a trial dispensary, I sat under a tree with Hassan. As we gazed up into the Usambara mountains, Hassan pointed to buildings that we could see in the distance and said, "Some villages are in remote spots since, during colonial times, people moved to places to escape German colonial taxation and took for the hills, setting up communities in the mountains and difficult to reach places." I had visited a few mountain villages with RTS,S trial staff when we drove trial participants and their caregivers home after trial staff collected health information, biometric data and blood samples from trial participants. One morning, I sat in the front of a trial van with Nelson, one of the trial drivers, as we drove people to their homes in the mountains. Although with other drop-offs we were able to bring people back to their villages, this time we had to drop off caregivers and trial participants at the end of a road. No cars could reach their mountain village so they had to walk the rest of the

way home. At that time, I gained a sense of how difficult it would be for people in this village to access medical care located at lower elevations.

Poverty and geography can play a role in people contracting malaria, as well as their ability to access the public health care system and malaria treatment. At the same time, from what I observed and understand of the literature, the Tanzanian health care system is resource-poor. For the health care providers that I spoke to, they felt proud of their contribution to the public health care system as they saw how it was saving lives. At the same time, they were keenly aware of limitations of the system, which at times constrained their ability to provide adequate care. Nevertheless, although resource scarcity was a big problem, I saw people who were not just coping but creatively engaging and adapting to various situations as they provided care. This finding resonates with what Wendland (2012a) found amongst Malawian medical students who were gaining clinical experience. These students adapted to circumstances in the resource-poor hospital where they were being trained. They learned to be creative and flexible and felt pride in their abilities to make do with less. For health care providers in Korogwe and Handeni Districts, part of their adaptation to circumstances was making use of trial staff and the resources they provided during the RTS, S trial. I now turn to focus on the health care and resources provided through the RTS,S vaccine trial, and the exchanges between the public and private health services.

# Trial-Funded Health Care, Exchange and the Maintenance of Boundaries

One morning at the Korogwe Research Centre, I spoke to Joseph, an administrator and doctor for the RTS,S vaccine trial. We discussed health care provision and he said, "In Tanzania the policy is that all the children under five and the pregnant mothers, they get free medical treatment, they don't pay anything." I countered this by saying, "But these facilities are not exactly the same." Joseph smiled and answered, "No, they are not the same (laughter) because in our trial we take much more care of those children.... More equipment, we provide them with free transport.... [T]his is the trial; we need to get data." During a second interview, after the RTS,S trial ended, Joseph said,

[W]e were providing free health care and the government hospital was also providing free health care at the same

time.... [T]he only difference is that in research we try to have all the drugs in stock for treating common childhood illnesses,... we tried to provide a minimum standard of care that was acceptable at international level. So, we [had] to make sure that we [were] there 24 hours, 7 days in a week, including ... public holidays. Whereas in a government [dispensary], you maybe see it's closed.

As Joseph discussed, the health care provided through the clinical trial was at a higher standard than what was available the public health care system, because the trial had to meet international ethical standards while also extracting information and tissue samples from trial participants.

Several trial staff spoke about how these resources and activities impacted the health of Tanzanians in and around Korogwe. Hassan said during an interview in the conference room of the Korogwe Research Centre,

> The trial [has] a very big impact because this project has been helping the people in this area. Not just the [trial] participants but even the people who come from the villages to this hospital. Because we [are] working hand-in-hand with this pediatric ward so we are not only helping participants, we are helping every child who enters that ward.... This lab here is helping every one in this area.... [W]e've been dealing with medical issues, even in the villages. We don't only treat in the dispensary or people who participate, sometimes other people come in and we still have to treat them because medically, you cannot let someone go,... we have to treat those cases. So, we are helping the people a lot.

Hassan thought, like many other informants, that the health care provided through the trial not only helped trial participants but the wider community, making it a valuable and beneficial service.

Other trial staff also spoke about this subject. I interviewed Caroline, a pharmacist at the Korogwe Research Centre, one morning in the conference room of the Korogwe Research Centre. She said, "There are people who cannot afford even 10 paracetamol tablets but because of the project, they are coming and being treated for free, whether they are coming as part of the study or not". I spoke to Emmanuel, a trial doctor, one afternoon in the conference room of the Korogwe Research Centre. He spoke about the technology provided through the trial:

The technologies have made a big impact, especially in the clinical site. If you take the rapid diagnostic tests for testing for malaria, many people, if they know this facility has the diagnostic tests,... will come to that facility instead of [going]

to the facility where there is no laboratory test. [If] there is a lot of diagnostic tests [being] done in the facilities you will see that a lot of people will go to that facility. Because many ... facilities, especially in the villages, they don't have those test [and] they don't have laboratories to diagnose.

As Emmanuel stated, many of the village dispensaries lack resources like mRDTs and laboratories. However, as Emmanuel argued, the resources made available through the RTS,S vaccine trial were available for people to access, which attracted people to use those facilities, leading to a "big impact", as he said, on the care people received as the trial was ongoing.

A number of trial staff spoke about how the health care provided through the vaccine trial positively impacted the community. It should be noted that this service enabled the RTS,S trial to operate and for GSK to adhere to international ethical standards and guidelines. Additionally, although RTS,S had been previously tested for safety and found to be safe for use in adults and children, it was important to track adverse reaction in participants in order to protect future vaccine users. Since health care was free of charge to users, participants were more likely to make use of it, allowing trial staff to collect data about the RTS,S vaccine. Hence, the provision of health care was instrumental, allowing GSK to monitor the impact of a new vaccine on the health of participants. The trial-provided health care was not provided as a free and charitable service, trial participants had to provide valuable information about the RTS,S vaccine in exchange.

Although several informants perceived the trial-funded health care service as socially valuable, its delivery was aided by various resources, including latex gloves, mRDTs, syringes and malaria medications. Caroline described the necessity for medical care resources: "There is a time when the kids get sick. You have to attend to them for a period of the study—three years. So, we have the pharmacy where we dispense the drugs to the trial dispensaries and also to the hospital where we have our study physician who will tend to them. So, we have to provide drugs and meet their needs, pharmaceutically." These materials and devices were made available through the establishment of drug and medical device procurement and supply networks. Caroline explained that the drugs and medical devices usually came from the nearby town of Tanga. The two trial pharmacists would locate three places to procure supplies and then "select the cheapest out of these three.... [W]e used to try as much as possible to get the cheapest supplier that we know, so most of this was from Tanga. And sometimes were used to get them in Dar es Salaam,"

Caroline said. Either she or the other pharmacist had to travel with a trial driver to pick up the drugs. "We couldn't send any other person [than] us to make sure that [the drugs were] genuine," Caroline said. "[T]his one time we were supplied with fake [drugs] and we returned it because ... we actually know what is a fake drug.... It only happened once and unfortunately it was from the government medical stores so it was quite tricky but at the end of the day they had to accept that it was fake and they had to take it back and return our money." This finding troubled Caroline who was concerned that fake drugs were circulating in the public health care system.

Once the drugs and medical devices were procured, they were stored in the pharmacy located in the basement of the Korogwe Research Centre. The Research Centre served as a conduit for materials, both enabling and constraining the movement and circulation of material resources (Geissler 2015b). Medical drugs and devices arrived and fieldworkers and health care providers moved them out to the pediatric ward and trial dispensaries. The basement where the pharmacy was located also had barred windows and doors that were locked at night. The entrance to the basement had additional protection from a metal gate and a giant lock to prevent unauthorized access and theft.

During the course of the trial, trial staff documented and tracked the movement and use of drugs and medical devices in log books and on paper forms. When trial staff in the Korogwe District hospital, trial dispensaries or villages needed more supplies, they filled out requisition forms to request them. These forms were delivered to one of the pharmacists, who filled the order. Once filled, fieldworkers transported supplies to trial dispensaries on their motorbikes, health care providers moved supplies from the pharmacy to the pediatric ward of the hospital, and fieldworkers picked up supplies they needed from trial dispensaries to use in villages. Procurement and supply networks made the trial possible and relied upon existing infrastructures, including roads, cell phone towers and the internet.

A site where trial-funded health care and resources were provided was in the Korogwe District Hospital, where the trial had been provided with use of the pediatric ward. Located near the Korogwe Research Centre, this made it easy for trial staff to move supplies there. As supplies moved to the District Hospital, filled out paper forms and tissue samples from children admitted to the pediatric ward moved in the opposite direction. The provision of health care and resources throughout the trial impacted how the hospital ward operated. Interviewing Simon, the Korogwe Research Centre site coordinator, one afternoon in his office, he said, "One of the

wards that is performing the best is the pediatric ward". Simon explained that the ward had been improved by hiring staff who worked entirely for the RTS,S clinical trial. Additionally, the ward had been improved through the regular supply of material resources made available through the trial. Neema, a trial data manager, also spoke about the impacts of the trial on the pediatric ward one afternoon in the data management office before the trial ended. She said, "Even the government staff used to say about this study, 'I don't know what we're going to do because it's organized, there is material available, there is medicine, compared to before the project started." Simon and Neema praised the impacts of the trial on health care delivery in the District Hospital and Neema, looking to the end of the vaccine trial, expressed concern about the level of care that would be available in the hospital at that time.

I spent time in the pediatric ward, watching how health care providers cared for people. To the left of the entrance of the ward was a small, dark office filled floor to ceiling with medical files, small cabinets and a refrigerator to store medicines. The main room of the ward was long in length with many screened windows spanning its length. Dusty ceiling fans slowly rotated but the air felt stuffy and hot despite them. Lit with florescent lights, the room contained 30 beds with blue mosquito nets hung over them. A television sat on a metal shelf near the entrance of the room, overlooking beds set aside for emergency cases but it was never turned on during the times I was in the ward. A few leafy plants were growing in pots around the room.

A large wooden table, situated near the entrance of the ward, was where nurses and doctors generally worked, filling out forms, providing vaccines, taking blood, and carrying out other tasks. The table had files, medical devices, paper forms, gauze and rubber tourniquets strewn across it. There were several wooden chairs and a bench around the table and nurses, in their bright pink scrubs, sat on these seats with caregivers and children. Mostly women came in with babies and children in their arms. People lined up to see a health care provider as others sat around the table so their children could be examined by a health care worker.



Figure 6: The pediatric ward of the Korogwe District Hospital.

Since there was no backup generator, the lights would turn off and the ceiling fans would stop their lazy rotations when the power went off from time to time. I watched caregivers and children cycle through the ward, leaving after treatment or being given a prescription, or being shown to a bed for treatment. Nurses with latex gloves used a glucometer to test children and employed syringes and sample tubes to collect blood from children. Caregivers and nurses comforted children and health care providers recorded diagnoses and prescriptions in new school exercise books that could later be taken to a pharmacist to request drugs. If a child was ill, health care providers asked caregivers questions and filled out paper laboratory forms to document information about the patient. When a child was a participant of the RTS, S trial, different paper forms were filled out to record names, biometric data and other information. These forms were then moved, along with tissue samples, to the laboratories at the Korogwe Research Centre. As Whyte (2011) argues, writing and recording information on paper are performances that transpire during medical research and during health care provision, affirming their similarity. However, the resources and well-paid staff in this ward set it apart from the other hospital wards, helping reinforce the differences between the public and privately-funded health care providers.

One morning as I was observing the ward, a man carried in his son who looked to be around three years old. The boy, dressed in jeans and a striped t-shirt, appeared very ill and fatigued, and clung limply to his father. The boy was a participant of the RTS, S vaccine trial and a nurse asked the father information about his son as she filled out paperwork reserved for those enrolled in the trial. Another nurse put on a pair of latex gloves, tested the boy with a glucometer and collected blood from a vein on the top of his hand, which was placed in a sample bottle. Barely conscious, the boy did not make a fuss over the procedures. A nurse tested the boy for malaria with a mRDT and found him to be positive. He was placed in a bed reserved for emergency cases and his father sat worriedly in a chair next to him as a nurse treated him. The blood collected from the boy was tested in the laboratory at the Korogwe Research Centre to confirm the malaria diagnosis. Asking Elijah, a trial doctor, how long it would take the boy to get better, he answered, "We anticipate 48 hours." Later that morning I asked Elijah what the benefits were of participating in the RTS,S vaccine trial. The doctor smiled and said, "Care. They are provided with quality care." What Elijah said echoed what Joseph expressed above, that health care was provided in exchange for participation in medical research. This exchange led to access to a high standard of care that was typically unavailable in the public health care system. Although this level of health care was provided from within a public health care facility, this standard set it apart from other hospital wards, reinforcing boundaries between public and private health care.

Early one morning I met Brayson, a doctor in the pediatric ward, to discuss the trial and the pediatric ward. Brayson was very knowledgeable and explained, "Malaria has gone way down in the past few years in and around Korogwe. Many of the children who come in with malaria came from villages far away from Korogwe. There is little malaria around here." Asking what accounted for the decline, Brayson said, "There is greater access to bed nets and ALu, arthemether lumefantrine [a type of malaria medication]". Although transnational donors have worked with the Tanzanian government to ensure access to bed nets and effective malaria medications, the RTS,S vaccine trial played an important role in providing bed nets and ensuring that the pediatric ward was regularly stocked with malaria medications and other drugs. For its involvement in the RTS,S clinical trial, GSK donated a glucometer to the pediatric ward and an X-ray machine to the entire hospital, both of which remained after the trial ended. The vaccine trial also helped people access free drugs when they were unavailable at the District Hospital.

Caroline thought the care and material resources provided to people in the pediatric ward obscured the boundaries between public and private health care. She argued,

For the people who come to *Magunga* [the Korogwe District Hospital],... they don't know that those drugs come from us.... A lot of patients don't know where drugs come from.... They don't know it is the study purchasing ... them. Once you tell the mother to go and buy [drugs], she doesn't understand.... The X-ray, they don't even know the machine doesn't belong to them, they just believe that it's the government.

It is understandable that users may have thought the care and drugs they received were provided by the public health care system. With the RTS,S clinical trial operating within a ward of a government hospital and providing resources like an X-ray machine directly to the hospital, there was no obvious division with the rest of the hospital. It would appear that the state was providing health care to children, as it had done for decades, only that the service had improved for three years while the vaccine trial was being conducted.

However, for health care providers and trial staff, the exchanges of material things made the differences between providers obvious. For example, I watched a few times when a nurse or doctor would come to the pediatric ward to ask trial staff to borrow the glucometer. Trial staff were generous and let people borrow it but government staff were unable to reciprocate. Rather than obscuring difference, this unequal exchange high-lighted that one ward had more resources through its private funding, while the other wards of the hospital remained resource-poor. Thus, the exchange of material things enabled people to see and understand the public health care system because an alternative system served as a comparison.

Exchange was an ongoing activity in dispensaries as well. With separate dispensary buildings constructed next to government dispensaries, it was obvious that different health care providers were in operation. The differences between the trial and government dispensaries were a point of discussion for several trial staff. Early one morning, I was sitting on the porch of a trial dispensary waiting for the first group of trial participants to arrive to have their blood drawn. Jackson, a trial doctor, came over to chat with me. At one point in our conversation, I asked him why he thought people joined the vaccine trial. He answered, "Most people join to access medical care, the emergency service and free drugs." He pointed to the building next door, the government dispensary. "Have you seen the health services

available from the government dispensary?" I nodded and said I had gotten a tour of the dispensary. The doctor nodded and said, "The trial offers better care than that."

Although health care providers at government dispensaries spoke about poor infrastructure, a lack of medications and medical devices, and being underpaid, the trial dispensaries functioned quite differently. As I was spending time at a trial dispensary, Fredy explained that a clinic officer was on call at all hours of the day or night to diagnose and treat ill children. If necessary, emergency care was provided and a trial car was sent out to dispensaries or homes to pick up sick participants and take them to the Korogwe District Hospital. Money was also provided to trial participants after consultations to cover the transportation costs incurred to visit the dispensaries. After Fredy provided care to a trial participant, I watched him give the mother some money and she hailed a mini-bus on the highway next to the dispensary. Fredy explained this transaction: "Often more money is given than what is needed to travel here and back home". This allowed the caregivers of participants to make some additional money from the visit.

The health care, emergency pick-ups, and transport reimbursement were material value transferred to trial participants and their caregivers. The health care and emergency pick-ups were services that benefit the RTS,S vaccine trial as well as trial participants, and were considered legitimate transfers of value due to their positive impacts on health outcomes. These activities also mirrored the public health care system, since health care, and at times emergency pick-ups, were provided to people in need. Money, on the other hand, is generally considered an illegitimate transfer of value and regulatory ethics guidelines for medical research assert that the provision of money should only occur to prevent cost and it is assumed that no personal gain is incurred. The concern is that payment for participation would induce people to participate where participation should be voluntary (Geissler 2011). However, transport reimbursement was a monetary transfer, and from what Fredy said, people were regularly given more money than what was needed to travel to the dispensary and back home. This would never be provided in the public health care system and this transfer of material value clearly distinguished medical research from the public health care system.



Figure 7: Trial dispensary next to a government dispensary.

Through the trial dispensaries, trial participants and community members could receive enhanced care. Each of the dispensaries built to support the trial were located near a government dispensary and when the government dispensaries were busy or experiencing stock-outs of drugs, government staff would direct caregivers with children to visit the trial dispensary to receive health care and drugs. One afternoon when I was spending time in a trial dispensary, a young mother came in with her infant who was breathing heavily. The baby was not a trial participant but the clinic officer examined the baby, placing a stethoscope on its tiny chest to listen to its breathing. He explained to the mother that her baby had an infection. The clinic officer gave the mother a handful of medications and marked the visit and the prescribed medications in a log book after they left. These drugs were provided free of charge from the trial's US\$7,000 a month drug budget.

Much like this interaction in the trial dispensary, health care and drugs are supposed to be provided free of charge to all Tanzanian children under the age of five when they visit government health care facilities. However, caregivers of sick children often had to see a pharmacist at a government facility or visit a private pharmacy to purchase drugs. Therefore, when people were provided with free care and drugs at a trial dispensary, this contrasted with the government health care system and made obvious what was publicly versus privately funded health care provision.

The resources made available through the RTS,S trial also benefitted people who visited government dispensaries. I observed many instances where trial staff provided free supplies, including syringes, latex gloves and other medical devices, to health care providers at government dispensaries nearby. One afternoon while spending time in the government dispensary, I was speaking with a nurse. She was explaining that she had just received boxes of Rapid Diagnostic Tests for HIV and malaria that week. She wanted to show me how they worked but discovered she was out of latex gloves. She went next door to the trial dispensary to request a pair and the clinic office was happy to oblige. Also, at times trial staff provided emergency transport to patients of the public health care system. For example, one morning at a trial dispensary, trial staff were collecting blood samples, biometric data and medical histories from trial participants. In a government dispensary next door, a pregnant woman was having trouble giving birth. A nurse helping with the birth went to the trial dispensary to ask for help, explaining that the woman had been in labour for hours and had stopped pushing, putting her and her unborn child in danger. The woman needed to have emergency care so the trial drivers and a government doctor bundled her up in the back of a trial truck and drove her to the Korogwe District Hospital, 45 minutes away. Once they had left I asked Erick, a trial fieldworker, how she could have gotten to the hospital without help from the trial staff. Erick said, "She would have had to take a *dala dala* [mini-bus] while in labour. She is lucky we were here." In this and other instances, trial staff provided care, time, labour and resources to help support the public health care system. Through these activities, the public health care system became more obvious, as emphasis was placed on how it differed in resources to the privately-funded health care services of the RTS,S trial.

The care and resources available from the RTS,S trial also flowed into the surrounding villages. A fieldworker lived in each of the villages participating in the trial and were called upon when a participant fell ill. Fieldworkers were trained in first aid and equipped with a thermometer, mRDT and first aid kit so they could diagnose children and treat them for non-serious illnesses. I interviewed Hassan and he explained how he and other fieldworkers provided care in villages:

As a fieldworker, we were doing passive and active case detection. This is when we attend the child at home. Maybe I was passing by and the mother calls me, 'Oh my son or daughter is sick'. When I go to help, that's what we call passive [case detection]. Then we were checking for

temperature and when a child had [a] fever, we were checking for malaria. When we checked for malaria and found that the child had malaria,... we [called the] physician to help us.... '[T]his child is malaria positive, what should I do?'... [I]f the case is complicated, we call the driver to take the child to the nearest [trial] dispensary to be checked by a [clinic officer].... [F]or the active case detection,... we ... visited the child once per month [in their home]. So, we went there and asked if the child had any adverse event in the last 30 days.

These two ways of providing health care, through passive and active case detection, meant that fieldworkers provided care when it was needed and also on a monthly basis in the homes of trial participants. Hassan explained that fieldworkers got to know people in the villages and also provided health care to children in the community when they fell ill. In this way, fieldworkers acted like community health workers, which have been in short supply in Tanzania in recent decades (Mubi et al. 2016, World Vision 2015).

The trial enabled the provision of care in trial dispensaries to participants and community members alike. Trial staff shared resources with public health care providers, care was provided through the District Hospital, and fieldworkers treated trial participants and other children in villages. From free drugs, to the sharing of latex gloves with government health care workers, to the diagnosis of every sick child admitted to the pediatric ward of the government hospital, the resources needed for the practices of care played a key role in health care provision during the clinical trial. Through its activities and placement in the District Hospital and villages, the trial was both a parallel health care provider and an embedded one. However, the boundaries between the two service providers were not blurred as Whyte (2011) and Leach and Fairhead (2011) found. Instead, through various exchanges, the distinction between medical research and health care were reinforced, as one service was significantly better staffed and resourced and could give more than the public health care staff could give in return.

# Cutting Ties: The End of the RTS,S Trial

After the RTS,S clinical trial concluded in December 2013, participants were, for the most part, left to make use of the public health care system. Gone were the emergency pick-ups and the internationally standardized laboratories which could

no longer sustain the diagnosis of children admitted to the Korogwe District Hospital. Fieldworkers no longer lived in trial villages to provide care to communities and trial staff no longer visited the homes of trial participants to ask about their health. Most of the trial dispensaries were closed until the Tanzanian government decided what to do with the spaces. The pharmaceuticals and medical devices that were once provided free of charge to trial participants and children in the community also stopped being available.

Trial staff anticipated the end of the trial and its impacts on health. Caroline remarked about the end of the trial-provided health care service,

They have been saying that if the study comes to an end, trust me, the pediatric ward will change, many deaths will be reported. What can you do? We can't do much.... How many deaths are going to ... happen in the pediatric ward?... Surely, they are crying that the deaths will be reported at a high rate but you can't have this every day. It has come to an end.

When I spoke to Brayson in the pediatric ward of the Korogwe District Hospital, he listed the various things the trial had provided to the hospital and then said, "There is no way the Ministry of Health can continue that without the trial's support." Both Caroline and Brayson described how the RTS,S trial supported service delivery. But that was time-limited, with many of the positive impacts ending when the trial came to a close. Despite the trial operating within the public health care system, Caroline and Brayson were asserting that the trial was unable to make long-lasting impacts. The trial staff had provided resources, labour and time to the public health care system but many of the issues the system faced were systemic, unimproved by time-limited medical research. In this way, boundaries were maintained between public and private health care provision since the private service ended as the public service, despite its underfunding, continued past the end of the RTS,S trial.

One afternoon I spoke with Hassan outside of a trial dispensary after the trial had ended. We were sitting in plastic chairs under trees by the side of the highway, looking at the government dispensary and the dispensary built to support the RTS,S clinical trial. As cars, trucks and buses rushed by, Hassan said, "Parents [of trial participants] are upset that the trial ended. They say they can't take their children to a good dispensary, there are no more emergency pick-ups. People have been using the trial dispensaries for a long time, they don't want to use the government dispensaries." Later he said, "I feel bad but they knew it was going to end. There is

nothing we can do." Hassan expressed a mix of loss, regret and defensiveness that the trial ended and left trial participants without well-funded health care services. He was also expressing that there was a limit to their responsibility to provide services for communities and trial participants.

I spoke to a malaria researcher working at the Korogwe Research Centre one morning as we were driving to the Korogwe Research Centre. He discussed the end of the clinical trial, which would mean the end of high quality medical care. He expressed a wish for the government to offer similar services. I asked which services the government should continue and he said,

There should be community health workers, kind of like the fieldworkers now, who could be stationed in each village, especially the villages that are far from dispensaries. These community health workers could be people to get care and information from, and they could carry out rapid diagnostic tests, like the [trial] fieldworkers do now.

This was a good suggestion and yet, the researcher did not know where the money would come for this and other much-needed improvements to the public health care system. The public health care system struggled to staff the health facilities that were already in existence and provide drugs. If the Tanzanian health care system were better funded, many of the services offered through the trial might be provided to all Tanzanians, regardless if they participated in medical research. However, currently, health system strengthening commands less attention than biomedical research to develop new pharmaceutical products (Gerrets 2010, Lachenal 2015, Geissler 2013).

Geissler (2014) and Crane (2013) found that when medical research drew to a close, health care provision and flow of material resources into impoverished places ceased. Researchers only provided health care to research participants when they were collecting data. Sustainable access to resources or lasting improvements to health care systems did not arise from the research and the research organizations did not change their mandates and become health care providers. As Geissler (2015a: 14) states, "research wards cannot change care standards in surrounding hospitals or dispense care after the end of a trial".

Many of the benefits of the trial were spatially and temporally bounded. The services and resource provided through the trial were not well-integrated into the public health care system and when the trial ended, the level of care and resources was unsustainable by a health care system that is highly dependent on donor

funding. This funding is usually directed towards disease-specific, vertical intervention programs, such as bed net or HIV drug distribution, not health system strengthening (THMIS 2013; Sullivan 2011). With the trial concluded, it became obvious that the health care, resources and infrastructures established over the course of the trial improved service delivery but were not part of comprehensive health system strengthening. Thus, the RTS,S clinical trial largely supported the building of research capacity, not medical capacity (Street 2014).

And yet, medical research laid the groundwork for demands for a better health care system. This relates to Wendland's (2012b) article about Malawian medical students who interact with foreign medical students who are visiting Malawi as clinical tourists. During this interaction, ideas circulated about how medical systems operated elsewhere, making obvious the unevenness of medicine around the world. Students constructed ideas about Malawian medicine against descriptions of medicine that clinical tourists provided and gained a vision of potential alternative futures. This created what Wendland calls a "medical imaginary"—a morally charged comparison between what is and what should be. But, for RTS,S trial staff, they did not need to meet people from abroad to get a sense of what an alternative public health care system was like; they saw this for themselves as they provided care during the vaccine trial. At the end of the trial, with many of the resources gone, several staff members expressed a desire to continue providing health care to people. As well, they gained a "medical imaginary", to apply Wendland's (2012b) term. They understood, first hand, how medical care could be provided and made demands for a better public health care system. Therefore, for trial staff, the health care provided through the RTS, S trial offered an idea of not only what could be, but what should be.

During the trial, excellent care was provided to trial participants and neighbouring children in order to minimize the possibility of harm, maintain international standards, and extract data from trial participants. Working out of the pediatric ward of the Korogwe District Hospital, dispensaries constructed for the clinical trial, and study villages, the RTS,S clinical trial established health care infrastructure and mobilized resources. Trial-funded health care facilities were staffed by well-paid people who had a regular supply of resources, including medicines, stethoscopes, syringes, and so on. This health care service stood in contrast to the public health care system, which had decaying infrastructure, underpayed staff and, at times, lacked drugs and medical devices.

Over the course of the vaccine trial, many exchanges transpired between the public health care system and the trial health care service. Although the public system provided space for the trial in the District Hospital and enabled the recruitment of trial participants, trial staff provided drugs, medical devices, labour, care and time. These exchanges reinforced differences between the two health services. This relates to theories of exchange that are derived from Melanesian ethnography. In these theories, social relationships, objects and people come into being through the exchange of objects, services and labour (West 2006; Knauft 1999; Strathern 1998). I argue something similar, that the exchange of material objects and labour between health care providers enabled the public health care system to come into being. Although people may have had an idea of how medicine operated in resource-rich places, the trial-funded health care service provided a direct experience of this kind of medicine. The privately-funded service had copious funding and due to the generosity of trial staff, more was provided to the public health care system than could be reciprocated. These exchanges between the two services made people clearly see the public health care system, with all its limitations and failings.

As well, when the clinical trial ended, so too did the health care and resources stemming from GSK and MVI, leaving trial participants and communities to use the public health care system. At the end of the RTS,S trial, it was evident that health system strengthening was unobtainable through this medical research because the medical care and the resources provided by the trial were both temporally and spatially circumscribed from the wider community and health care system (Street 2014). For trial staff, this ending of health care provision was unsettling. They had been shown how medicine could be otherwise but then that service disappeared. There was a sense of loss as informants felt unable to offer social justice or change social inequality, and some discussed their responsibility and its limits in relation to constrained funding and research mandates (cf. Geissler 2015b). However, others appeared to develop a "medical imaginary", seeing how things could be different. Some expressed a desire and sense of duty to continue to provide care, while putting forth political demands for these services to be continued (Wendland 2012b). Thus, through the RTS,S vaccine trial, the public health care

system came to be seen and understood as people gained a sense of how things could be otherwise. Although the vaccine trial made several material impacts on Tanzania, it also had an additional effect: shaping people's ideas and visions for the future.

# Chapter 5: Blood and Paper: Tracing the Collection, Transformation and Movement of Evidence During the RTS,S Clinical Trial

# Introduction

Speaking to Sharon, a representative of the Malaria Vaccine Initiative (MVI), via internet video call in June 2015, she explained the aim of the RTS,S vaccine clinical trial:

I always say, 'The data is the deal'. You could not justify doing a study and potentially putting children at risk with an untested vaccine if you weren't going to have interpretable data and complete data that was reliable and accurate.

As Sharon explains, the central aim of the vaccine trial was to produce data that indicated that the RTS, S vaccine protected children from malaria. This data had to be reliable and accurate in order to justify endangering children with an untested vaccine. In order to produce reliable and accurate data, evidence was collected about the safety and ability of RTS,S to prevent malaria amongst African children. This evidence needed to be portable, reproducible, comparable across the other Africa vaccine trial sites, and generalizable to other places in Africa. In order to produce evidence, the RTS,S vaccine trial was organize into a randomized control trial (RCT), as described in chapter 1. Once every child received three doses of the malaria or an alternative vaccine, evidence about the efficacy of RTS,S was collected over a two year period (RTS,S Clinical Trials Partnership 2015). During this time, trial employees collected blood, biometric data, medical histories, and information about the malaria prevention strategies employed by caregivers on behalf of trial participants. Although much of this information was quantitative in nature, some was qualitative and/or self-reported and was not statistically analyzed like the quantitative data. However, this qualitative data helped researchers understand the impact of prevention strategies and other behaviour on malaria rates and health outcomes amongst trial participants.

Trial staff in Korogwe scrupulously followed the internationally recognized procedures and rules for clinical trials set out in documents such as the International

Conference on Harmonization-Good Clinical Practice Guidelines (ICH-GCP) (Petryna 2009; Simpson and Sariola 2012). Speaking to Simon, the site coordinator, one afternoon in his office at the Korogwe Research Centre, he explained GCP and how it impacted trial activities:

The tool that is driving this trial is guidelines, GCP guidelines.... It is important that the staff [are] adhering to these guidelines,... instructing us how to work and how to behave professionally.... [Y]ou must sign and you must document because at the end of the day you can be audited. If you do things that which are contrary to GCP ... you can be questioned.... To keep that standard is important for the accuracy of the data we are collecting.

Quintiles, a United States (US)-based Contract Research Organization (CRO), audited documents on a regular basis to ensure staff were following GCP guidelines. Faithfully following GCP guidelines guaranteed acceptance of the trial results by broader scientific publics, including drug regulators and journal audiences. Acceptance of the results of the clinical trials allows the RTS,S vaccine to enter international markets in the future (Simpson and Sariola 2012).

Throughout the trial, staff collected evidence in the form of human blood and information that was recorded on paper and digitally entered into computers. This blood and information was transformed, analyzed and moved while increasingly being refined and abstracted to generate quantitative data. Blood, a main source of evidence in many clinical trials, is laden with evidence. As Carsten (2013) and Whyte (2011) argue, blood is of the highest quality material in medical research, thought to reveal the truth about a body. This truth is borne out by machines, which identify qualities of the blood that cannot be perceived by humans. Although blood is often the main source of evidence in medical research, paper is often far more universal and helps people record, store and move information (Whyte 2011). The information stored on paper can be digitized using computers, enabling its movement and analysis away from sites where the data was collected.

The production and collection of evidence through the RTS,S clinical trial across Africa relates to the growing push for and use of quantitative metrics in global health over the last few decades. Increasingly, global health institutions and pharmaceutical companies are reliant on the production of evidence in the form of quantitative metrics to develop new drugs or health interventions. This has been accompanied by complex transformations in funding, interventions and audit. A key way that metrics are produced is through statistical measures and experimental research, including clinical trials (Adams 2016a and 2016b). Generating evidence about the efficacy of a new drug or intervention helps build public support for global health activities (Rottenburg 2009).

In search of places to produce credible evidence about interventions and drugs, medical experiments are increasingly globalized (Petryna 2009). Bench scientists are linked to sites of critical care, places where socioeconomic inequalities—and inequities in health care access and disease that accompany them—have produced ideal conditions to conduct research (Adams 2016b; Street 2014 and 2016; Nguyen 2015). This research attempts to determine the effectiveness of a treatment through something that approaches a 'real life' setting and situation (Strathern 2011). The places where experiments are conducted become "truth spots" (Gieryn 2006) for the production of credible data. The outcomes of these experiments are imagined to be scalable and reproducible, like those carried out in pharmaceutical laboratories. The knowledge accumulated in these experiments can be universally translated and circulated globally as a measurement of biological efficacy (Geissler 2013; Adams 2016b; Nguyen 2005; Street 2016).

To support field research, often Northern research institutions and pharmaceutical companies set up field stations and laboratories in Southern countries (Crane 2013; Okwaro and Geissler 2015). With this configuration, transnational medical research operates on terrains marked by vast inequalities. Research stations and laboratories in the South become sites of exchange and extraction with objects, people, money, knowledge and other forms of value circulating between places (Adams et al. 2005; Crane 2013; Geissler 2013 and 2015a). Although this movement and exchange could be conceived of as an open flow around the world, there are uneven and historically shaped ways that people and things move over space and time and contemporary medical research can reinforce historical and existing inequalities (Anderson 2009; Anderson and Adams 2008; Adams et al. 2005). Furthermore, some anthropologists (Petryna 2009; Crane 2013) argue that research can function as a form of exploitation as Southern research sites supply Northern-funded science with knowledge that can lead to the development of new medical interventions, drugs, or vaccines.

While attention to the inequalities and hierarchies that shape transnational medical research is important, so too are the social and relational aspects of data collection. Biruk (2012) argues that despite the assumption that the numbers

produced by research projects are simply collected from the participants of research, quantification is a social and cultural process. The numbers that are produced through research are social artifacts, derived from complex negotiations, relations and exchanges with a range of people. But through the process of knowledge production in medical research, complex issues and places are transformed into manageable and mobile forms, with much of the information about people and places excised or ignored. This process leads to important aspects of social interaction and relationality being disregarded throughout research, and unrepresented in the final research findings.

Examining the collection of evidence in the last month and a half of the RTS,S clinical trial, this chapter looks at the process of evidence collection. Conducting ethnography, I was well-positioned to observe the social aspects of evidence collection. I slow down the data collection process to describe the ways in which RTS,S clinical trial staff collected, fragmented, analyzed and moved samples and information. I draw attention to the exchanges, expressions of affect, and the social interactions and relationships that mediated evidence collection, as well as the caring labour that trial staff provided to trial participants and the data that was collected. Trial staff were middle figures who were position between their Northern partners, who were hierarchically above them, and community members in Tanzania, who were hierarchically below them. Through affect, social relationships, exchange and care, trial staff handled a situation that was fundamentally unequal, making incommensurate experiences of data collection commensurate. Trial researchers in Tanzania and their Northern partners at GlaxoSmithKline (GSK) and MVI did not see these aspects of research, as they were focused on the collection of particular kinds of data that could be abstracted and quantified. However, I argue that without social relationships, care, exchange and affect, the development of the RTS,S vaccine would not have been possible.

In this chapter, I first provide background on the epistemology of medicine and the process of evidence production and collection. Secondly, I explore the process of evidence collection, with a focus on specific materials—blood and paper—which were important sources and recorders of evidence in the clinical trial. I also attend to the various social aspects that mediated this evidence collection. Finally, I trace blood and paper as they were moved, analyzed, digitized and prepared for travel out of Tanzania.

#### Producing Credible Evidence

The RTS,S malaria vaccine was tested in a large-scale, double blinded, RCT. In medicine, there is a hierarchy of knowledge and large-scale RCTs are considered the "gold standard" for producing knowledge about the effectiveness of an intervention (Timmermans and Berg 2003; Kachur 2011; Ecks 2008). Randomization of participants in experiments was developed in 1946 by Anthony Bradford Hill, a professor of medical statistics and epidemiology at the London School of Hygiene and Tropical Medicine. Bradford Hill was exploring the effects of various treatments in human experiments and wanted remove confounding factors. In order to do this, he placed human subjects of an experiment into random groups. He then added blinding into the experiment, where the investigator does not know which human subject received the treatment or the placebo (Kelly 2011). As Engelke (2008: S17) argues, the concern about the role of human (i.e. biased) intentions in corrupting scientific experiments led to "methodological precautions," including the use of RCTs and blinding, which are thought to take human intentions out of the production of evidence. This form of not knowing is a source of validity for experiments, producing knowledge that is regarded as trustworthy and reliable (Engelke 2008; Geissler 2013).

Since the 1980s, evidence has increasingly become fundamental to health policy and research (Lambert 2009). This initially began in Northern countries and spread globally in association with economic and political agendas and forces (Kachur 2011). Although the systematic evaluation of data about the effectiveness of an intervention was originally promoted through clinical epidemiology, this has expanded across the medical discipline and been called "evidence-based medicine" (EBM). The role of evidence in medicine is to determine the effectiveness of interventions in order to improve practice and health outcomes. This evidence ideally provides strict comparison across interventions, hence the need for quantitative and standardized experiments. With EBM, clinical practice uses the 'best' evidence available to inform decisions for treatment. The rise of evidence in medicine can be related to a decline in trust of authority and a desire for increased transparency and accountability (Lambert 2009).

Anthropologists have critiqued RCTs—and EBM more generally undermining claims of epistemic authority. Lambert (2006) argues that the emphasis on producing credible medical evidence marginalizes or excludes the

social dimensions of illness and disease, allowing little understanding of the role of social, economic, political and cultural dimensions in shaping health outcomes, despite their important role. Ecks (2008) argues that a weakness of EBM is its inability to question disease entities and diagnostic criteria since it carries the assumption that everyone understands problems in the same way. Kachur (2011) explores the limitations of RCTs as a form of evidence production when examining a clinical trial conducted in Tanzania. He argues that RCTs are unable to replicate real world conditions. Through the provision of health care and limiting of enrolment into studies, trial activities alter settings to a degree that they no longer resemble the real-world contexts where the intervention will ultimately be delivered. This means that the experimental design can have little generalizability or external validity.

Moreover, as Adams (2016a) argues, experimental studies impact how people and place are understood and thus intervened upon. Producing credible numbers requires estimation that deliberately erases key specificities about mortalities and morbidities crucial for intervention. Whyte (2011) draws attention to paperwork and writing that happens during medical research. She writes, "Knowing about people involves taking an epistemological perspective on them" (30) and that the collection of knowledge about people allows for the abstraction of data and knowledge about African health. Experiments therefore do not simply lead to observations and recordings of things that are happening out in the world. Through the following of forms and questions that standardize things like disease categories, excluding important information for understanding disease and illness, and the practices of limiting enrolment and providing health care to participants, RCTs make worlds and selves (Ecks 2008; Whyte 2011; Kachur 2011). However, despite anthropologists highlighting issues with RCTs, in global health—and medicine more generally-there is an ever-increasing need for credible evidence. The movement for an evidence-based medicine is linked to an ever-growing academic-industrial complex, which ensures its continued funding through calls for more experimental studies (Kachur 2011).

Other anthropologists explore issues of power and hierarchy, drawing attention to the ways that transnational medical research leads to dependency and inequality. Crane (2013) in Uganda, Tousignant (2013) in Senegal, and Okwaro and Geissler (2015) in East Africa have each found in their research sites that information and tissue samples were collected, preliminary analysis was conducted in African laboratories, and information and samples were exported to Northern

institutions for further analysis. As these anthropologists note, when evidence was collected in Southern research sites and moved North to be analyzed, hierarchies and inequalities were established. This situation leads to dependencies, relegating Southern scientists to performers of basic tasks of conducting preliminary analysis on fresh samples and sending samples and data abroad. Researchers in the North have the technology to conduct complex analysis in the increasingly molecularized field of global science and can provide the theories that make the science understood to wider audiences.

Some have argued that since research operates in situations marked with inequality, it can be a form of exploitation. Knowledge has become Africa's new export and its production and movement can benefit Northern institutions because they have the means to translate that knowledge into academic papers or products (Petryna 2009; Janes and Corbett 2009; Whyte 2011). This situation relates to the Latourian idea of "at a distance," whereby knowledge collected by the powerful about those less powerful creates centres where knowledge is accumulated, leading to asymmetries of knowledge and consequently, power (Latour 1987). More than that, medical research produces evidence that can promote new interventions and drugs, allowing for the production of wealth. Once an intervention or drug is found to be efficacious through research, companies and organizations can monetize it, selling it to global health organizations, health care systems, or users. Thus, experiments and the knowledge produced from them underpin business enterprises and profit. This connection between RCTs, evidence and new health interventions expose the connection between neoliberal profit seeking and global health. By drawing this connection between evidence and profit, it is clear why the knowledge accumulated through experiments would be considered highly valuable (Adams 2016b; Erikson 2012). Yet, this profit does not always equally benefit the people and places that provided the knowledge (Crane 2013).

Beyond this critical perspective on evidence production and collection in transnational medical research, it is important to pay attention to the social process of evidence collection. Biruk (2012) contends that the quantitative outputs of research are obtained through exchange, social negotiations and relationships with many people. However, the epistemology that underpins medicine gives credence to particular kinds of evidence over others. Thus, the standards that govern data collection transform the complexity and dynamics of a place or social engagement by ignoring or excising potential information. Through the process of data collection,

researchers do not simply miss information; they see what they aim to see. Simplifying complexity and excising social engagement allows for the collection of information that is more manageable and mobile. Research projects simplify practices and people because they create representational fixity and stability and work to manage uncertainty. This process means that social relationships and interactions are absent from the way people see and understand scientific research. Therefore, researchers do not only miss seeing these aspects, they do not understand how vital these aspects are to the research.

This exploration of the literature demonstrates that evidence plays a key role in medicine and global health. Critical perspectives on evidence collection draw attention to the inequalities and hierarchies that can accompany transnational medical research. But in particular, it is the literature about the social and relational aspects of data collection and scientific research that I build upon by exploring the material, social, affective and caring aspects of evidence collection. Below I explore how information was collected during the RTS,S vaccine trial.

#### **Collecting Evidence during Home Visits**

When I arrived in Korogwe in November 2013, I saw teams of nurses and fieldworkers leave the Korogwe Research Centre each morning. Wondering where they went, I asked George, a nurse working for the RTS,S trial, about these trips. He explained that fieldworkers and nurses visited each trial participant in their home every month to collect information. These staff were given a one-page paper form to fill out during their visits. This form had a series of questions written on it with boxes to check and spaces to write what trial staff found at each home. These visits helped determine if trial participants were in good health and if and how caregivers were preventing malaria. Since the trial was winding down, trial staff only had a small window of time to catch participants and their caregivers at home.

Wanting to observe this trial activity myself, I accompanied Hassan, a trial fieldworker, on a hot December afternoon as he visited surrounding villages with a motorbike. On the motorbike, we drove by the tall and green Usambara Mountain range and headed away from Korogwe along the highway. A German construction company was rebuilding the highway so there was plenty of dust and gravel.

Hassan joked, saying, "Europeans always said Africa is dusty but it's because we're always fixing our roads!"

After about 45 minutes on the highway, we turned off and drove quickly up a steep dirt road to visit two houses in a village built on the side of the tall hill. Hassan waved and called out greetings to people he saw as we drove by. We arrived at a mud brick house with a tin roof and a number painted in large white writing on the wooden entrance door to indicate that a trial participant lived there. Hassan knocked on the door and a neighbor emerged from the house next door and said that the mother was away. Hassan told the neighbor that he would return the next day. During this exchange, many people crowded around, curious about us. People called out to Hassan, saying "*daktari*" [doctor] to him in greeting. Hassan seemed embarrassed by people calling him a doctor and said to me, "I'm not a qualified doctor but people don't realize this." He explained that he had gotten this moniker during the second phase of the trial when he used to diagnose and provide treatment to children in this village when they became ill.

Getting back on the motorbike, we moved onto the next house that Hassan needed to visit that day, which was by the side of the main highway. This house was made of cinderblocks painted in bright pastel colours and had a tin roof. Hassan explained that the tin roof and cinderblocks, as well as its close proximity to the highway, indicated that this was an affluent family, compared to the last home we visited. When we knocked on the door, a teenage girl opened it and, greeting us, said, "*Mambo*". Hassan said "*Mambo vipi*" in return. Hassan explained who he was, showing the girl his trial identification card. Hassan explained that he was there to ask questions about the trial participant who lived there. The teenage girl nodded, said she was the older sister of the trial participant and was willing to answer questions about her little sister.

Hassan pulled out the one-page paper form for home visits from the satchel he wore over his shoulder. The form had a series of questions on it as well as a name and number corresponding to the trial participant. Hassan read off the form, asking the teenage girl questions about the home and the trial participant. The first question Hassan asked was about whether the home had received Indoor Residual Spray (IRS), an insecticide spray to kill mosquitoes. If a house has received IRS, mosquitoes that land on the sprayed surfaces later die, decrease the mosquito population and thus the number of people who become infected with malaria (Crawley et al. 2010). Hassan explained to me that with fewer mosquitoes transmitting malaria, this can make the RTS,S malaria vaccine appear more effective in preventing malaria and could thus affect the interpretation of the trial data. Although IRS could affect the results of the clinical trial, trial staff did not discourage people from getting IRS in their homes. GSK wanted to know about use of this spray so that it could be included in the interpretation of the trial data. The teenage girl answered Hassan's question, saying the house had not received IRS in the last month and Hassan checked a box for 'no' on the form next to the first question.

Hassan then enquired about whether the trial participant slept under a bed net each night. Like IRS, the use of a mosquito net can lower the chances of contracting malaria and can make the RTS,S vaccine appear more effective at preventing malaria. GSK needed to know this information to analyze the vaccine trial data. The teenage girl answered that her little sister did sleep under a net and Hassan recorded this on the form. Hassan also wanted to know about the state of the bed net, asking if it was ripped with a hole bigger than three adult fingers across. He demonstrated to the teenage girl how big that was by holding up his hand with his three middle fingers pushed together. Although the insecticide found in the plastic of the mosquito net stops mosquitoes from entering small holes, if a net has a tear big enough to allow three fingers through, mosquitoes would be able to get into the net. The teen said the net did not have big holes. Hassan asked to examine the net himself but the teenage girl explained that the bedroom was locked and the only key was with her mother. The mother had left early in the morning to plant food crops far away from the home and would not return until the evening.

Hassan asked if the trial participant was there, if she had been ill in the last month and if he could see her. The teenage girl said that her little sister had been well and then brought Mary, the trial participant, out to the porch of the house so Hassan could see her and make sure she was healthy. Mary looked to be about three years old and was wearing a lime green dress. Hassan explained that he knew Mary from his many previous visits to the home and she seemed comfortable with him. Hassan picked her up and asked me to take a picture as he smiled widely. I took the picture and Mary burst into tears as she looked at me in doubt. Hassan put her down, trying to comfort her. The teenage girl put Mary inside the home and Hassan told the teen that he would have to return the next morning to see the mosquito net. Hassan showed me the form he was filling in and said that once completed, he would deliver it to the data office in the basement of the Korogwe Research Centre. Data managers in the office would type the information Hassan collected into computers, which would be uploaded to a server made available to data cleaners in India and data analysts at GSK in Belgium. Completing this online process triggered an invitation to the next visit, which would involve the collection of information and a blood sample from Mary and her caregiver the following week.

The monthly visits to the homes of participants produced information about their health and use of malaria prevention methods. As part of the ongoing collection of evidence throughout the RTS,S clinical trial, the information produced from home visits helped account for factors that could affect the interpretation of the trial data. These visits were also a way to monitor the health of participants on a regular basis and allowed trial staff to keep in regular contact with participants and their caregivers. At the same time, the work that trial staff like Hassan were doing was being counted and becoming a metric. For example, Hassan and other fieldworkers had to visit homes, fill out paper forms and deliver them to the Korogwe Research Centre on time or find themselves unemployed.

Visits to the homes of every participant every month produced piles of paper which became digital information that moved away from Tanzania and became evidence about RTS,S. However, this paperwork had a narrow list of questions and boxes to fill in. In this way, the paper form allowed for knowledge to be recorded and stabilized while not allowing for other information to be recorded. For example, there was no room to record how Hassan interacted with people, despite the importance of this in enabling the trial to be conducted. Therefore, the process of collecting a small subset of information while eliding the rest shapes how the world, people, and the research itself are known and understood (Whyte 2011; Biruk 2012).

## Paper Forms and Invitation Cards

Once home visits were completed, the next step in evidence collection could occur. After visiting Mary's home, Hassan needed to deliver invitation cards to the homes of participants. We stopped at a hotel beneath a steep mountain that provided a rest stop for bus passengers traveling between Arusha and Dar es Salaam. There, Hassan showed me the invitation cards. They were printed on thick, yellow card paper and were meant for participants who had already received a home visit in the last couple of weeks and were ready to have blood and information collected as part of the final step of the RTS,S trial before it ended. Hassan filled out these invitation cards with the names and date of birth of the participant, names of the caregivers, name of the village, and the date and time of the dispensary visit using a list that the data managers at the Korogwe Research Centre provided. As Hassan carefully filled in the invitation cards, he explained that people got their last names from the first name of their father, pointing out that pattern on the invitation cards. Hassan then said that caregivers had to bring these invitation cards with them to the upcoming dispensary visit to aid trial staff in finding paperwork for participants. These cards were printed on thick, brightly coloured paper so they could both stand up to wear and tear and enable caregivers to spot them easily. Thus, the material composition of the invitation cards was chosen to convey its importance to those who received them in hopes that they might remember to bring the card along with them to the dispensary.

Hassan and I set out on the highway again until we reached a village that was built on the side of a steep hill. Hassan was able to gun the motorbike enough to get us up most of the way but the hill became too steep for the motorbike so we parked by a path and walked the rest of the way up to a house. There, we found a woman and her child by their mud brick house. Hassan waved and said, "Mambo!" in greeting. He whispered to me that the parents were hearing impaired. We were approaching the mother and child when the father joined them from a nearby field that he had been tending. Hassan needed to see the child's identification card, which had been issued to them by trial staff at the beginning of the study, to provide the invitation card to the parents. In order to communicate this, Hassan brought out his identification card and then pointing at the child. There was some confusion for a few seconds and then the mother started nodding and ducked into the house and came out with the card. Hassan checked that the numbers on his form and on the identification matched. He showed me this and I was able to see that the child was named Abasi and that the picture on the card was of the mother holding the child when he was an infant. Now Abasi could walk and shyly stood behind his mother looking up at us. Hassan returned the identification card and gave the mother the invitation card, pointing to the date and time he had written on it. The mother nodded and Hassan and I waved goodbye to the family and left the village. We

continued on motorbike until we had delivered five invitation cards to homes in two different villages. After this, we returned to the Korogwe Research Centre in late afternoon.

In order to understand the data collection process better, I spoke with Neema, a data manager. It was an afternoon in December and I visited Neema in the basement of the Korogwe Research Centre. Data managers were hard at work, typing information into laptops. The air was stuffy and the office loud but not wanting to disturb the staff, Neema spoke softly. She showed me the different forms for collecting information about participants during different kinds of visits and the thick, yellow card paper used to print invitation cards, which were kept behind her desk on shelves. She also showed me the computer programs used to track participants. Neema explained that different groups of participants were on slightly staggered schedules for home visits and dispensary visits based on when they were first vaccinated. She said that once a participant was vaccinated three times, that information was typed into the computer program and the program indicated when home visits and dispensary visits should occur. The computer programs made it easy to keep track of trial participants and plan for each step of the trial.

For example, in Abasi's case, Hassan had visited the participant's home to collect information on his health and use of malaria prevention methods. Hassan dropped off that filled out form to the data management offices and data managers typed that information into computers. This triggered the computer program to produce a date for a dispensary visit and a date for invitations to be delivered to Abasi's parents one to two days beforehand. We then delivered the invitation card to Abasi's parents and Hassan reported that to a data manager who typed that information into the computer program. The program then instructed data managers to prepare paperwork for the upcoming dispensary visit, including a five-page form to collect biometric data and health history, and a one-page laboratory form. Each step involved paperwork and digitization and allowed for the collection of evidence about Abasi. However, there was no room in this process to represent the importance of social interaction in the collection of this data, leaving this aspect undocumented and unseen by researchers at GSK. Next, I explore the collection of biometric and health information from trial participants.

## **Collecting Biometric and Health Information**

With home visits completed and invitation cards received, it was time for trial participants to visit a trial dispensary near their home. Anywhere between 10 and 40 of the 1,500 trial participants were invited at a time, each accompanied by a caregiver, until eventually almost every participant attended a dispensary. The purpose of this dispensary visit was to update records with new height, weight and upper arm circumference data, medical histories, and blood samples. A team of doctors, nurses and fieldworkers carried out the data collection. After these activities were completed, a small sample of blood and some numbers and letters written on paper forms were produced.

At the Korogwe Research Centre before heading out to a dispensary, trial staff placed paper forms, blood drawing devices, plastic furniture and other things needed for data collection into a large white van and two pick-up trucks. Tagging along with the team one morning, I squeezed into the back of a truck with two nurses and a beat-up Styrofoam box holding over-stuffed binders filled with information about participants. The Styrofoam box had been filled to the top with two layers of binders and I could see that each binder had a number on its spine corresponding to a participant identification number. As we drove up into the Usambara Mountains, the air cooled as the grey skies overhead threatened rain.

Arriving at the trial dispensary, I saw that it was situated close to a government dispensary and shaded by a number of trees. The trial dispensary was painted white with an open-air porch surrounded by a low concrete wall where people could sit. There were three rooms in the dispensary and wooden benches were arranged on the porch in rows facing the rooms. A few trial staff had arrived earlier and had set up plastic chairs and tables, as well as a scale and several thermometers. Several binders filled with participants' files had been laid out on the plastic table. After dropping off staff at the dispensary, trial drivers left to pick up trial participants and their caregivers and bring them to the dispensary.



Figure 8: Trial dispensary.

Once caregivers and participants arrived at the dispensary, they sat on the wooden benches and waited for their child's name to be called by a nurse. At the table set up on the porch, a nurse and fieldworker filled out the first page of the five-page form with information found in participant files, including the name of the participant and their caregiver, name of their village and sub-village, name of the village leader, house number, and date of birth. Once this was completed for each participant, the nurse and fieldworker began calling out the name of participants. This was a signal for caregivers to bring their child to be seen by the nurse and fieldworker who took each child's temperature by placing a thermometer under their arm. Once taken, the temperature was recorded on the form. If a fever was discovered, that was noted in the file, which signalled to trial staff that the child would need to be tested for malaria using a Rapid Diagnostic Test for malaria (mRDT) after their blood was drawn. Each child was weighed on a scale, and their height and their arm circumference were measured, with this information recorded on the five-page form.



Figure 9: Trial participant files in Styrofoam box.

Most children were calm during this process but some cried. A few children looked scared but the nurse was able to reassure them or make them laugh as she weighed and measure them. One little boy became very upset when the nurse tried to take his temperature. His mother looked embarrassed and apologized to the nurse while trying to get the child to accept having his temperature taken. The nurse gave the boy a lollipop in an attempt to appease him, but in the end the mother and nurse had to hold the boy down so they could get a reading from the thermometer. A few children cried when the nurse approached them and refused to step on the scale to be weighed. Caregivers helped calm and reassure these children by holding their hands or speaking softly to them. All of these interactions slowed down the process of collecting biometric data and trial staff attempted to conceal their frustration and calmly deal with participants and caregivers, even as they felt the pressure to complete the process quickly so participants could move onto the next stage.

After biometric data was collected and recorded, children and caregivers return to the benches to wait for their turn to be called by a trial doctor. The nurse and fieldworker matched the partially filled-out forms with participant binders and added them to the back of the binders. A fieldworker then moved each of the binders into the consultation room of the dispensary. The two trial doctors in the consultation room received the binders and called out the names of participants, one after another, to enter the consultation room. Caregivers responded by bringing their child to see the doctor and would usually sit in a seat next to the doctor, placing their child in their lap.

Watching one interaction, I saw Joseph, a trial doctor and administrator, greet the participant and her mother with a big smile. Joseph said, "*Habari ya asubuhi* [Good morning]". The mother responded with "*Shikamoo*," an expression used by an inferior to greet a superior. The doctor responded with "*Marahaba*", the usual response after someone says *shikamoo*. The doctor then looked at the child, a little girl, and greeted her with "*Mambo, habari yako* [Hello, how are you?]" The child was shy but with encouragement from her mother she responded with "*Nzuri* [good]". The doctor had the girl's binder open to the second page of the five-page form and asked the mother about any health issues the child might have had recently. She responded and the doctor wrote the information he was given on the form. Joseph then examined the child and wrote his findings on the form. Finding the girl had an infection, he wrote information about the medications he prescribed to her on the third page of the form. Speaking with the mother, Joseph also collected information on the administration of non-licensed drugs, including traditional remedies.

A little later, Joseph called out the name of a participant, a little boy, and found the child was accompanied by his older sister, who looked to be about ten years old. Joseph asked the sister about the health of her little brother but she was unable to answer him, not knowing if the boy had been ill within the last month. Joseph appeared annoyed as he began examining the boy but remained calm. In the end, he filled out the form as best he could but sections remained empty. Speaking to Erick, a fieldworker, after this interaction, he explained that sometimes siblings and other family members bring participants to the dispensary because parents are busy or away farming that day.

A few children put up a fuss during the consultation, making it difficult for doctors to examine them. Caregivers and doctors tried to sooth and console children during the process or cheer them up with a joke or a hug and these actions helped smooth the process.

This collection of data involved trial staff engaging in particular kinds of labour, including the expression of affect, provision of care, and socially interacting and negotiating with children and caregivers in creative ways. As described in chapter 2, trial staff were trained to interact with trial participants and community members in calm and caring ways, which is what I observed of trial staff, even in

situations that might have been frustrating or annoying. These interactions were not represented in the final results of the trial or seen by people at GSK or MVI but were integral to helping the RTS,S vaccine come into being.

After doctors completed their consultations, they placed the nearly completed five-page form back into the participant's binder. Next, a fieldworker moved the binders into the small room next to the consultation room. This room was where blood was drawn. Many children grew increasingly upset as they heard the wails of other children having their blood drawn in this room. Caregivers comforted children but eventually each participant was called to provide blood.

# **Drawing Blood**

A child whimpered and then cried out as a nurse inserted a needle into the top of his hand. The child pulled back his hand and his mother, who was holding him in her lap, grabbed his hand to hold it in place and allow a trial nurse to finish collecting the child's blood. The child stared at his hand and wailed and then started to repeat, "Pipi, pipi", over and over, begging for a lollipop in Swahili. His mother whispered in his ear, trying to comfort him. The nurse, with a look of concentration on his face, removed the tourniquet from the top of the child's hand. Dark red liquid filled the thin, long plastic tube connected to the needle and the blood flowed into a small plastic sample bottle. Once the sample bottle contained enough blood for the laboratory technicians to conduct analysis, the nurse withdrew the needle from the child's hand. The nurse stoppered the bottle and a fieldworker placed a piece of cotton swab on the child's injection wound and applied pressure to stop the blood from flowing. The child quieted down and was happy when the nurse gave him a lollipop. A fieldworker showed the mother how to gently apply pressure to the child's wound. With tears still on his face, the mother led the boy out of the small, cramped room and onto the porch of the dispensary to wait to be taken back to their home.

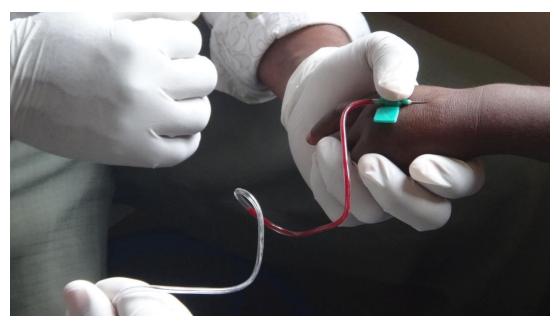


Figure 10: A nurse drawing blood from trial participant.

The four men in the small dispensary room, a nurse and three fieldworkers, had anxious looks on their faces as they dealt with the 38 children who needed their blood drawn and laboratory paperwork filled out. They felt constrained for time as they worried that trial participants and caregivers may grow frustrated with waiting and agitate to leave. As well, they were all aware of the necessity to collect blood quickly and deliver it to the laboratory before it degraded. Once a child had their blood taken, the fieldworker who was filling out laboratory forms, called out for the next child to enter the small room. A little girl in a shiny orange dress entered with her mother. The mother sat on a chair facing the nurse and placed the girl in her lap. With the needle coming close to her hand, the little girl demanded a lollipop. Usually children were given a lollipop only after their blood was drawn so the nurse was hesitant to comply. However, he wanted the girl to cooperate. About to hand the little girl a lollipop, she suddenly demanded two lollipops, sensing she might continue to get her way. The nurse gave the girl what she wanted and everyone in the room laughed. A fieldworker remarked, "What a future business woman!" and smiled at her with admiration. This little girl was aware that this situation was a transaction and she sought the best exchange she could get.

Though children were not often as demanding as that little girl, many expected a lollipop after their blood was drawn. *"Nataka pipi!* [I want a lollipop!]" many would yell or demand, seeing the sweets on the counter in front of them. Staff found giving into the children's demands made the whole operation run smoother.

However, not every child cried, some were quiet and others were fascinated to watch the blood leave their hand and flow into a clear plastic tube. But most ended up in tears when they realized what was about to happen. This was not their first time experiencing a blood draw but given their age, many did not remember the last time they had blood drawn for the trial. Hassan sat at a plastic desk in the room to fill out paperwork and said, "They are lucky this time to have only one vial of blood to give. During other times, they had to give two vials of blood or get a vaccination."

During this process, trial staff provided care to participants. There was always an additional fieldworker in the room to help distract an upset child about the prospects of having their blood drawn by joking or commiserating with them. If a child resisted having their blood drawn, this extra fieldworker would hold the child's hand steady so the nurse could insert the needle. This fieldworker also held younger siblings of trial participants when they accompanied them into the room. This freed caregivers to hold trial participants in their lap as their blood was drawn. Parents appeared to appreciate this caring labour, often thanking the fieldworker as they left the room.



Figure 11: Lollipops and instruments for drawing blood.

After each blood draw, the nurse moved the sample bottle to the table where Hassan sat. Hassan had pages of barcode stickers that corresponded to each participant and he matched each bottle of blood with a barcode. He then filled out the part of the five-page form that ordered laboratory test. This part of the form included spaces to indicate how many bottles of blood were taken and what laboratory tests needed to be carried out. Since sample bottles contained an anticoagulant that lasted four hours, there was a space on the form to indicate when the blood was drawn, which was crucial information for laboratory technicians to know how much time they had to analyze and process the blood. Hassan also filled out laboratory forms with the name and identification number of participants and where the blood samples were taken. Matching barcodes were stuck on the laboratory form and the blood sample so laboratory technicians could later connect the blood samples with the participant's paperwork. Hassan moved quickly, calling on a trial nurse to give him more binders filled with participant files. At the same time, Erick, a fieldworker, was testing the blood of participants who had a high fever using a mRDT. If the child was found positive for malaria, a trial doctor prescribed medication to treat the infection and the positive test results were packaged with the blood samples to be taken to the laboratory at the Korogwe Research Centre.

Only a small subset of information about the participant was of interest to the trial and the aim was to collect vast amounts of data about this narrow subset. What was left of the encounter was a small vial of blood and some numbers and letters written on paper detailing biometric and health information. Although this process involved many people, social interactions and exchanges, these details were unimportant to trial funders and not recorded (Whyte 2011; Biruk 2012). Within hours, the collected blood and information was fragmented, refined and transported, moving further from the source.

## The Movement and Fragmentation of Blood

Once every participant had their blood drawn, Erick transported the blood samples, positive mRDTs and laboratory forms to the haematology laboratory at the Korogwe Research Centre via motorbike, taking special care of these things. He delivered them to laboratory technicians who had to sign a form that they received them. Blood was an important substance for the production of evidence. It was a substance exchanged at great cost, or so it seemed as I watched children cry and whimper in fear and pain during the blood drawing procedure. Laboratory technicians, aware that the anti-coagulant chemical in the small sample bottles was only active for a few hours, carried out blood analysis and preparation in the early afternoon, only a few hours after the blood was drawn.

As described in chapter 3, there were two laboratories at the Korogwe Research Centre. Located at the front of the Research Centre, the haematology laboratory was where blood samples were tested. Wearing white laboratory coats and latex gloves, laboratory technicians conducted different parts of the blood processing, analysis, and documentation. Wilson, a laboratory technician, supervised three other laboratory technicians. Much of the paperwork was completed in the entrance room where there were two long tables and several chairs positioned against the two walls. To the left of the first room was where blood slides were stained with dye and examined through a microscope for malaria parasites. The room contained a purple stained ceramic sink for washing and drying the slides. There were two long tables along the two walls, two microscopes, files, a log book, two small, metal tally counters for counting the number of parasites found in the slide. Floor to ceiling shelves spanned half of one wall and was filled with plastic cases for storing blood slides. The room to the right of the entry room was large with several grey tables. The tables held a centrifuge and two blood analysis machines and space to prepare blood slides. Several barred windows allowed natural light into the space. Instructions for handling blood samples and other forms were tacked to walls and bulletin boards and there were two tall metal filing cabinets full of folders, binders and forms.

Given a white plastic laboratory coat and a pair of latex gloves, I observed the blood analysis process. Nathaniel, a laboratory technician, carried out the first stage of the analysis using a machine to test the blood samples. The samples Erick had brought in were in a plastic bag. I noticed that some samples looked dark red in colour, others quite light. I pointed this out to Nathaniel and he explained that the difference in colour related to the level of haemoglobin: the darker the colour, the more haemoglobin present and healthier the participant, indicating not only that they were not suffering from anaemia but that they may have better nutrition. Although Nathaniel could observe this blood characteristic visually, he waited for the blood analysis machine to determine a quantitative measure of this characteristic so it could be included in the documentation sent to GSK in Belgium.

Taking one of the small blood sample bottles out of the plastic bag, Nathaniel shook it ten times between his thumb and index finger to mix the anti-coagulant in the sample bottle with the blood. He then removed the purple stopper of the bottle. The blood analysis machine sat on a table in the laboratory and Nathaniel keyed the identification number of the participant into the machine so the resulting paper

printout would be properly labelled. Placing the open sample bottle beneath a long needle, the machine sucked up a small amount of blood from the bottle with an audible sucking sound. Waiting a few minutes, the machine printed out results on a small, thin piece of paper. It detailed 19 numerical blood characteristics, including white blood count and haemoglobin level. Once all the blood samples had been analysed by the machine, Nathaniel matched and glued the resulting printouts to the corresponding laboratory forms that Hassan had filled out at the trial dispensary in the morning. As the print-out from the blood analysis machine was photosensitive and would later fade, the forms were photocopied twice, with one copy kept on file in the laboratory and another copy taken to the data management office in the basement of the Research Centre to be entered into computers.

Once the blood was analysed by the machine, Paul, another laboratory technician, affixed drops of blood to small pieces of filter paper. Shaped like miniature greeting cards, filter paper was thick and absorbent. Blood was placed on the inner part of the filter paper, which was closed with a sticker on the outer edge to prevent tampering. The filter paper would later be analyzed in a laboratory outside of Tanzania to determine the malaria parasite genotype that infected the participant.

Afterward, Nathaniel made blood slides from the remaining blood in the sample bottles. Using a thin needle to suck up some blood, he placed a drop of the liquid on a small, thin and rectangular shaped piece of glass called a slide. He quickly swiped the blood across the slide using the long side of the needle, making the blood transparent and easy to look through with a microscope. Two slides were made per trial participant and then left to dry overnight, to be stained with purple dye the next morning. After this, the slides were ready to be analysed. Nathaniel used one copy of the slide to count the concentration of malaria parasites in the blood using a microscope, documenting on paper forms the number of parasites he found. Once the slides, filter paper and paperwork were completed, each item was labelled with a participants' identification number and barcode to identify who the samples and paperwork belonged to. One copy of the slide remained in Korogwe. Another copy of the slide—along with the filter paper—were sent to a laboratory in Johannesburg, South Africa run by Quintiles, the US-based Contract Research Organization (CRO), that oversaw the RTS, S vaccine trials. There, the results found in Korogwe would be verified and samples would be analyzed at the molecular level to find malaria parasites.

Wilson checked the paperwork for errors and signed off on the work. The paperwork was in duplicate; a copy remained in the laboratory for future auditing, and another copy was sent to nurses, doctors and administrators to review before it was sent to the data management office in the basement of the Research Centre to be digitized. Thus, as the blood was being subdivided, the data representing the trial participants was also being subdivided with only bits of information transported out of Korogwe.

As Nathaniel and Paul worked, I asked them if they had visited a trial dispensary or any of the study villages and they smiled and said no. Nathaniel said, "The blood we test is not connected to the people who give it." I said to the laboratory technicians, "At the dispensaries, some children cry and fight, not wanting to get their blood drawn. But others are fascinated with seeing their blood flow out of their hand." Paul and Nathaniel laughed at this description, surprised. Nathaniel said, "I never think about the people who provide the blood. I only know [participants] as ... numbers, which helps with confidentiality and objectivity. I like it that way because I can get on with the work, concentrate on doing the tests." Thus, the person who provided the blood did not need be known personally, the 'truth' about him or her was in their blood, born out of the refinement and analysis carried out in laboratories (Carsten 2013).

Tanzanian children provided blood samples and the resulting blood became increasingly fragmented and processed. This resulted in the production of paper forms, quantitative data and blood that could be stored and analyzed later in laboratories outside of Tanzania. Blood was a kind of evidence that held 'proof' about the efficacy of RTS,S since it contained information about participants' health and immunity to malaria. This richness of information made blood important for the production of evidence. However, this blood needed to be modified, transformed, moved abroad, and analyzed at the molecular level. The haematology laboratory at the Korogwe Research Centre was not equipped to do molecular analysis. The need for sophisticated molecular analysis of blood samples required clinical trial funders to invest in expensive machines. GSK and MVI decided that rather than supplying African research centres with these machines, African researchers would prepare and send blood samples abroad to laboratories that were better equipped.

The entire process of blood analysis and completion of paperwork involved hours of work. Although the focus of the RTS,S trial was on the production of quantitative findings, the laboratory technicians demonstrated care for the materials

they worked with, carefully moving, fragmenting and transforming the blood as they documented their procedures and findings. Laboratory work is usually conceived of as the dispassionate manipulation of objects. However, care and affective labour played important roles in the laboratory work for the trial, enabling evidence production (de la Bellacasa 2011).

#### Following the Files: Paperwork, Movement and Digitization

As laboratory technicians analyzed and fragmented blood in the haematology laboratory, other trial staff completed paperwork. At the trial dispensary, staff had filled in most of the five-page form. Once the first four pages of the form were completed, Angela, a trial nurse, matched each form to a participants' binder and placed the form inside. Then Angela looked through participant files for mistakes. Showing me what she was looking for, she came across typos and boxes unfilled. One of the trial doctors, Brayson, had written the wrong date on a number of pages of a form. Exasperated, Angela yelled out in a friendly way to Brayson, who was in the room next door, that he needed to fix his mistakes. When Brayson arrived, she pointing them out, saying "QC" repeatedly. Brayson smiled and fixed his mistakes. Angela laughed and Brayson explained to me that "QC means quality control." Angela continued to check that the forms were completed properly and once satisfied, the binders were placed into Styrofoam boxes and loaded into a trial van to return to the Korogwe Research Centre.

At the Research Centre, the Principal Investigator (PI) filled out the fifth page of the form to document any adverse events that participants had experienced, if participants were withdrawing from the study, and if so, the reasons why. The PI then signed and dated each form and placed them back into their corresponding binders. Afterwards, trial nurses, doctors and the principal investigator checked the files for mistakes. Once all the forms were completed, Hassan, Erick and other young and able-bodied staff members moved the overstuffed binders to the data management office in the basement of the Research Centre.

Once the paperwork was moved to the data management offices, a team of six data entry employees typed the information into computers, digitizing it. There was constant movement in this office as staff shared forms, flipped pages and picked up heavy binders filled with paperwork. Electronics hummed, an air conditioner pumped cold air into the room, and people typed on keyboards.

When I was observing this office, I asked Victoria, one of the data management staff, what she was typing. Victoria explained that she was dealing with "anthropometric data". The computer page she was filling in had boxes and spaces for a name, weight, height, and body temperature. Victoria looked at a patient file beside her to find the information to type into the computer. Two other women were typing data into laptops using forms that came from the laboratory that detailed the blood analysis results. Other staff members were entering data that had been collected earlier in the clinical trial or typing in information about past vaccine use in children, so that people at GSK knew what vaccines were provided to participants along with RTS,S.

I spoke to Neema, a data manager, about activities in the data management office. She explained that some staff entered data and others took care of the files to ensure they were stored properly in the archive. Another staff member cared for the archive by organizing files and monitoring the temperature and humidity in the room. Ibrahim, the head data manager, and Neema managed the staff and organized the data management spaces. When there was a lot of paperwork after a dispensary visit, all the staff pitched in to help digitize the data. But on days when there were few children, a few staff members worked on digitizing data collected from previous years of the trial.

Neema said that data managers tried to avoid making errors as they entered data into computers but errors were difficult to avoid completely. In order to catch errors, the data typed into computers was "cleaned", meaning mistakes and inconsistencies were found and corrected. Each piece of information was typed into computers twice by two different staff members, which allowed inconsistencies to be found between the entries. Ibrahim showed me the program that helped clean the data. This program searched for duplicate entries and inconsistencies in those entries. If inconsistencies were found, staff went back to the source document to find the correct data.

Once cleaned, the data was uploaded to a central server. The central server made data instantly available to data managers at GSK in Belgium via a satellite connection. Through this connection, GSK monitored ongoing data entry activities in Korogwe. The central server also had a physical backup on a hard drive locked away in the Korogwe Research Centre. The data was sent to a data cleaning company in India for additional cleaning. From India, the more polished data was sent to GSK for review and further analysis.

Data management staff in Korogwe spent a large part of their time answering queries made by data managers and researchers at GSK and in India. Neema said, "There are [queries] that are automatic, others … review the data and they send the queries. So, we reply to them and correct what they want us to correct." Trial staff received upwards of 100 queries a day to answer. When queries were sent, staff had to look up information in files or seek blood slides to help resolve discrepancies between what was on record in Belgium and what was on record in Korogwe. Neema found a list of queries on a piece of paper on Ibrahim's desk to show me an example of a query. The paper had a list of questions written on it and she pointed to one question that asked about the time a blood sample was taken. Data managers in Belgium found a discrepancy between the time on record there and what was on record in Korogwe. To answer this query, staff looked up the patient file to find the original paper form and confirm the time written there. Then they updated the digital file with the correct time. Neema shrugged and explaining that the query was commonplace, saying, "It is easy to make little mistakes or typos."

After staff digitized the information that had been recorded on paper, the paper files were moved to the data archive room, a space filled floor to ceiling with shelves for all the binders of patient files. Visiting the archive with Neema, I could see that the paper files were protected with doors that had heavy locks. I had to sign a visitor's log book when I entered the archive and Neema explained that entry into the archive had to be monitored by a member of senior staff to make sure no information was tampered with or removed. The space was cool and an air conditioning unit worked at all times to keep the files protected from the heat and humidity outside. The archivist who oversaw the archive had already pulled out binders for the participants attending the dispensary visit the next morning and placed them in a couple of Styrofoam boxes. Beside the shelves of patient data, there was a small desk and two laptop computers set up with a direct connection to Belgium so if staff at GSK posed a query about a patient file, staff in Korogwe could answer the query in the archive, without having to remove files from the room. At the end of the basement hallway was another room that held participant binders for the second phase of the RTS,S trial. These files had been digitized years before but the paper files were preserved.

Every month, staff from Quintiles visited the Korogwe Research Centre for further verification of the data. When staff from Quintiles arrived in Korogwe in December, there was a palpable tension at the Research Centre. Quintiles staff

spent four days at the Research Centre, with most of their time spent in the archive in the basement. They compared paper records to the computers records, trying to find mistakes or inconsistencies. If these were found, staff at the Research Centre corrected them. Observing some of this work through the door of the archive, I could see Quintiles staff looking through laptops and files, tersely asking data managers questions. Once the staff from Quintiles left, the principal investigator told me that the staff at the Korogwe Research Centre had done a good job and that not many mistakes had been found. With the audit finished, staff returned to normal trial activities.

Paperwork was an important aspect of evidence production and its creation was an ongoing process throughout the trial. Trial activities were documented in detail, according to what GSK and drug regulators wanted to know about the RTS,S vaccine. Trial staff collected data at several points during the trial, including during the signing of consent forms, vaccinations, monthly house visits, and dispensary or hospital visits. Staff completed forms, checked boxes, fixed mistakes and stored information on paper. Following GCP guidelines, each of those forms was signed by a member of staff so the work could be traced and audited if ever there was a mistake. And at each step, trial staff put caring labour into the paperwork. From forms being filled out, to paper being moved, digitized and stored, staff were meticulous and careful. They moved it, handled it, cleaned it and kept it cool. These caring practices were necessary for the conduct of the trial and for RTS,S to be developed.

Although the information that was recorded on paper was eventually digitized, the paper files remained important. Paper served as stable source of information, a way to trace trial activities after they occurred and keep staff accountable to their work. In these ways, paper was ubiquitous and essential material in the vaccine trial. Also, writing research findings on paper objectified the knowledge that was collected and allowed it to be published and circulated amongst scientists who weighed the findings against existing knowledge found in other published papers. Furthermore, the value and significance of the scientific knowledge collected throughout the trial may continue into the future, even after its creators have died (Whyte 2011). However, due to the international nature of the vaccine trial, paper had its limitations. Since the trial was being conducted at eleven sites and in seven African countries, digitization of the information recorded on

paper was necessary so the data could be collected and analyzed in one place. I now explore why blood and information was moved abroad.

## **Moving Evidence**

RTS,S trial staff spent a lot of time preparing blood samples and information to be sent abroad. The blood moved from the trial participants, to the Korogwe Research Centre, and some moved onto South Africa and Belgium. The further away it got from the source, the more the blood was analyzed and refined. The information collected and recorded on paper was later digitized moved from Tanzanian to India and then onto Belgium. Through movement and transformation, the evidence collected in Tanzania built credibility and authority as medical evidence. The evidence was valuable and allowed RTS,S to be evaluated by drug regulators, a necessary step towards entering the market.

Why did further analysis need to be conducted outside of Africa? Grace, a laboratory technician, discussed the limitations of the laboratories at the Korogwe Research Centre in her office one afternoon after the trial had ended:

[E]ven in this lab, we don't have the molecular [facilities] and now, most of the research goes to the molecular level but we don't have the molecular. We still have to ship things abroad. But if we had the molecular facilities here, we would be doing everything here. Even the immunological parts, we have to send them to GSK, they are [doing] the immunology research there and we don't have it here. Even some of these machines, they require a lot of money to maintain and reagents [come] from abroad, that can be an issue. Most of the machines are coming from abroad, so we were having issues with [border] clearance.

Here, Grace explains what is missing in the laboratories at the Research Centre and the difficulties with obtaining machines that can do molecular and immunological analysis. During our discussion, she cited barriers at border control for obtaining machinery and the steep costs of maintaining scientific equipment when reagents need to be bought and machines need to be maintained by technicians from abroad.

There were also limitations for analyzing the data produced by the trial. Speaking to Ibrahim one afternoon in his small office in the basement of the Korogwe Research Centre, he touched upon the collection, digitization and cleaning of data and its movement to India. He speculated that trial funders had outsourced the cleaning of the data to India because of the cheap labour cost there. But it was more than labour costs that led to the movement of data out of Africa. Curious why the data was sent outside of Africa for further processing, I spoke to Michael, a representative of MVI. He said,

> Maybe [the data processing] could have been done in Africa but we were getting hit with budget limitations.... Also, it would involve trying to create a system when there was already one that could handle it. These contractors in India were set up ... and they had the track record.

Moving evidence out of Tanzania to be analyzed in established centres for evidence analysis made financial sense to funders. Why build scientific capabilities in Africa when those capabilities existed elsewhere? Not only was it cheaper to do this, it was considered a safer choice because the Indian data centres had a history of producing quality data cleaning services.

By applying a critical perspective on the process of evidence collection, transformation and movement at the RTS,S vaccine trial in Korogwe, I find similarities in what Tousignant (2013), Crane (2013) and Okwaro and Geissler (2015) found in their field sites when scientific samples collected in Africa are shipped abroad. By not building the capacity of researchers in Tanzania to conduct molecular analysis, or creating data analysis centres, Tanzania largely served as a place where raw materials were collected and prepared for export. Tanzanian children provided blood and they and their caregivers provided information. Researchers at the Korogwe Research Centre were given just enough scientific capability to process the blood in a preliminary fashion before it degraded. It was then sent to laboratory technicians at Quintiles in South Africa to conduct molecular analysis of blood samples and verify results found in Korogwe. As well, despite the blood and digital data first flowing south and east after leaving Tanzania, the data ultimately moved to GSK in Belgium. There, researchers completed the analysis and polished the end product, preparing it for presentation to drug regulators, policy makers and scientific journals. This complex analysis and synthesis in Europe increased the value of the evidence with the blood and information recorded on paper shifting from material product to intellectual property. Knowledge, data, money, drugs and other kinds of value circulated beyond Tanzania and researchers in Korogwe were unequal players in this global health research (Geissler 2015a; Tousignant 2013). The means of producing credible data largely remained in wealthy places in the North, while researchers in Tanzania had little capacity to

conduct the same analysis, making them dependent on wealthy donors and partners (Crane 2013; Okwaro and Geissler 2015). This production of evidence holds similarities to relationships of production during colonialism and could be construed as similarly exploitative (Turshen 1984; Crane 2013; Biruk 2012).

However, by taking a feminist approach to science, I uncovered that scientific knowledge production is more than materiality or inequality. Science, including the process of evidence collection, refinement and movement during the RTS,S trial, is mediated by a range of social interactions and experiences. Although unrepresented in the research findings, social relationships, affect, exchange and care enabled the collection of evidence throughout the RTS,S clinical trial.

In this chapter, I attended to the material and social aspects of evidence production, collection, analysis and movement. Trial staff collected blood and information from trial participants and caregivers and transported them to the Korogwe Research Centre. There, the blood was fragmented, analyzed, translated into letters and numbers, and prepared for transportation, and the information was checked for accuracy and digitized. The information and blood were transported to laboratories and computers outside of Tanzania for further analysis. In many ways, this arrangement helped maintain unequal relationships between Northern and Southern partners.

With only a subset of information recorded throughout these proceedings, this simplified data collection (Biruk 2012). But what was missed in this data collection was an attention to the social aspects of science, which I was well-positioned to observe. Trial staff interacted and connected socially with trial participants, caregivers and other staff members. A multitude of exchanges occurred between trial staff, trial participants and caregivers, some of which facilitated or created difficulties in social relationships. Staff experienced affect, with moments of connection, misunderstanding, frustration, annoyance, joy and laughter. They also cared for trial participants, paper forms, laboratory equipment and blood. These aspects, although unrecorded during the trial and largely unseen by Northern partners at MVI and GSK, were of great importance because they enabled not only the RTS,S clinical trial to operate in situations of inequality but for the RTS,S vaccine to come into being.

## Conclusion

By exploring the development of the RTS,S malaria vaccine, this dissertation examined global health partnerships. There has been a meteoric growth of partnerships in global health over the last two decades. Gaining popularity in the late 1990s, partnership has ascended as a guiding principle, becoming a dominant mode of engagement and encouraged by new funding models. It derives from the idea that complex health issues in low-resource countries cannot be dealt with by individual organizations working in isolation but necessitates partners collaboratively combining strengths, pooling resources, and sharing burdens and benefits. Partnership has played an important role in transforming global health and even critics have come to see partnerships as an "unavoidable necessity" in combating infectious diseases amongst the world's poor (Richter 2004: 45; Gerrets 2010; Buse and Walt 2000).

Forming a new governance structure, partnerships have commanded great financial resources and come to be highly influential, transforming thinking and practices (Gerrets 2015; Buse and Walt 2000a and 2000b). Until the rise of partnerships, life-saving products were either unavailable to a majority of impoverished people or had not been invented. During the decades before partnerships, health issues afflicting the poor were largely ignored by private and public sector institutions that failed to devise solutions or develop much-needed products (Gerrets 2010). Partnerships have been promoted as a way to overcome the weaknesses of the private and public sectors. Since coming to prominence, partnerships have advocated for disease interventions; improved access to drugs and other health interventions; and advanced research and development of interventions and products (Buse and Harmer 2007).

A considerable amount of partnership activity has been around product development which aim to develop vaccines and drugs for diseases that primarily affect the poor. Linking products to markets where there is a need but lack of economic incentive or resources, product development partnerships have made great progress in developing vaccines and drugs for infectious diseases (Widdus 2005; Chataway et al. 2007b; Buse and Walt 2000a). At the same time, the development of vaccines, drugs or medical devices has necessitated medical research in the places where they will be deployed. In order to support this, partnerships have been formed between Northern and Southern institutions (Street 2014; Chataway et al. 2007b; Crane 2013).

Although many global health partnerships are recognized for saving numerous lives, transforming drug and vaccine development for infectious diseases, the partnership model raises some important questions and concerns (Gerrets 2010). Partnerships can shift the distribution of power amongst organizations and may not lead to mutuality and equality between partners. The use of the term, 'partnership', which has an ambiguous meaning, may disguise unequal power relations and allow for the perpetuation of Northern domination over the South (Buse and Harmer 2007; Abrahamsen 2004; Crewe and Harrison 2008). Criticism has been raised about the role of the private sector, including industry and philanthropic organizations, in global health. This involvement may shape the global health agenda to benefit industry or the wealthy few over health systems (Birn 2014; McGoey et al. 2011). There is also concern that partnerships tend to focus on technical problems and single diseases. Related to this is the push for the development and delivery of technical solutions and targeted interventions to tackle ill health, which accounts for the considerable funding channelled towards product development partnerships. However, this situation can lead to a narrow focus on vertical programs, which can undermine holistic approaches to illness and primary health care services (Petryna 2009; Biehl 2016; Birn 2014).

Despite these concerns, little empirical research has been conducted on global health partnerships, though there is a small, albeit growing, body of anthropological literature about global health partnerships. Anthropologists have examined global health partnerships from various perspectives: a few (Brown 2015; Street 2014; Sullivan 2011) have explored public-private partnerships from within hospitals located in the South. Others (Gerrets 2015; Crane 2013; Okwaro and Geissler 2015) investigate the role of North-South partnerships in medical research. And Nading (2015) examines a product development partnership. While some of these anthropologists focus on the narratives of the people involved in partnerships, or examine partnerships as they are ongoing, none look at partnerships when they are in the process of ending. This is a culminating moment when affect, meaning and ethics are heightened. My anthropological investigation of partnerships formed between GlaxoSmithKline (GSK), the Malaria Vaccine Initiative (MVI) and a Tanzanian research institution to develop the RTS,S malaria vaccine provides an approach to understanding how people engaged with and reflected upon

partnerships as they were winding down and after they had ended. This period of time evoked reflections amongst informants about the past, present and future as they tried to understand the impacts of the RTS,S trial, the partnerships, and their involvement in these activities and relationships.

Central to many anthropological accounts of global health partnerships are the themes of hierarchy and power. This critical perspective is important and salient to many aspects of partnerships. But what is often missing in institutional readings of partnership is a close-up exploration of partnerships.

I was able to conduct ethnographic research as partnerships were in operation and catch moments of affect and exchange, explore people's imaginaries for the future, and observe caring labour. Through this thesis, I have explored questions about partnerships, including: How do global health partnerships operate and what happens as they end? What kind of impacts do partnerships have on the places where they operate? What are the roles of infrastructure, technology, social relationships, affect, exchange, and practices of care in the operation of partnerships? These questions inspired a critical materialist and feminist analysis of partnerships and are addressed in each of the chapters of the thesis.

Chapter 1 contributes to the social science literature about product development partnerships (Nading 2015; Chataway et al. 2007a; Chataway et al. 2010; Kale et al. 2013). I explore through first-hand accounts and secondary literature how product development partnerships operated as they were ending and after they concluded. This chapter provided historical and scientific background on RTS,S vaccine development and described technical and scientific advances over time. I also uncovered the social relationships that enabled the RTS,S vaccine to be developed. Partnerships were formed between various institutions and companies to fund, research and test the vaccine. Many of these partnerships were formed among Northern actors but later in the development of the vaccine, partnerships were established between North and South in order to test the vaccine in Africa. These North-South partnerships engendered particular kinds of relationships as people navigated hierarchy and vast differences in wealth and expertise. Although these later partnerships were largely perceived and portrayed as equal, many informants referenced relations of power by speaking to the inequalities and hierarchies between partners. However, some trial staff demonstrated the ways they contended with the incommensurate aspects of partnership. This included downplaying inequality or looking to a time when the RTS,S vaccine would save

lives. This chapter builds on anthropological accounts (Crane 2013; Okwaro and Geissler 2015; Gerrets 2015) of research partnerships between Northern and Southern institutions and researchers while it expands our understanding of how differently positioned people reflect on partnership and rationalize inequality.

In chapter 2, I add to the scholarship on international development projects (Mosse 2005; Li 1999; Crewe and Harrison 2008), which examine the technical and social aspects of intentional and time-bounded projects that bring together a variety of people around development issues. As well, by drawing out the perspectives of Southern researchers and their Northern partners, this chapter builds upon anthropological research and bioethical debates (Kelly and Geissler 2011; Kelly 2011; Molyneux and Geissler 2008; Chantler 2012; Emanual et al. 2004) about the value and ethics of medical research conducted in resource-poor settings. The focus of this chapter was on how informants perceived the impacts of the RTS,S vaccine partnerships and clinical trial on Tanzania. Several spoke about the success and value of the trial, beyond the development of a malaria vaccine. These included the building of human and material capacity, improving the health and education of communities, providing bed nets, and the establishment of social relationships and partnerships with community members. I argue that people were enrolled in an "interpretive community", to apply Mosse's (2005) term, whereby people had an interest in portraying events and activities as successful because they each benefited professionally or personally from the RTS,S partnerships and clinical trial. As well, since my research was conducted as the partnerships and trial were winding down or after they had ended, this impacted narratives as people shared their hopes, aspirations, and imaginaries for the future. Through interviews and discussions with me, informants may have desired to reassure themselves that they had engaged in valuable and meaningful work. This may have helped people grapple with endings, ambiguous outcomes, and unequal relationships with their Northern partners.

Chapter 3 builds upon theoretical and anthropological analyses of infrastructure and technology by exploring the material impacts of the RTS,S clinical trial and partnerships in Korogwe and surrounding areas. GSK and MVI funded the provision of technology and the construction of infrastructure and buildings. By drawing on Mauss (1990 [1925]] and Malinowski (2014 [1922]), I argue that these investments were gifts. Although Northern partners expressed satisfaction with providing these material objects and several trial staff members claimed they

improved research and health care capacity, these material things had ambivalent impacts. This became obvious at the end of the RTS,S trial when funding from Northern partners ceased to support research activities and health care services. The material things were enclaved, decaying, and required ongoing care and maintenance. This exposed hierarchies between Northern and Southern institutions, whereby African researchers were dependent on wealthy funders to conduct research.

Tanzanian trial staff experienced the materials things given to them by their Northern partners in an ongoing way and continued to maintain them in hopes of attracting new research partnerships. This relates to theoretical understandings of infrastructure as a way to progress and develop. But Northern partners disengaged from their obligations to the material things. This chapter contributes to the scholarship on global health partnerships by demonstrating a new understanding of partnership. First, partnership is not simply a rhetorical device that is empty of meaning; partnership can become meaningful as people come together to care for material things and develop a technology. Second, only one side of a partnership needs to be fully believed in and inhabited to mobilize people's affect, care and labour in supporting it and its material manifestations.

The fourth chapter contributes to the anthropological literature about exchange, medical research and health care provision. Throughout the trial there were numerous exchanges between the RTS,S trial health care service and the Tanzanian public health care system. I draw on anthropological theories of exchange that uncover that people, social relationships and objects can come into being when services, objects or labour are exchanged (West 2006; Knauft 1999; Strathern 1998). I extend this theory to argue that the exchange of labour and material objects between the public and private health care providers allowed the public health care system to come into being. The trial-provided health care service was well-resourced and shared with the public health care system in exchange for use of the pediatric ward of the Korogwe District Hospital and enabling the recruitment of trial participants. However, these exchanges were not reciprocated in an equal manner, with the private health services providing more than the public health care system. This made the differences between the two health care services obvious to people.

Moreover, at the end of the RTS,S clinical trial, health care services and resources largely ended, demonstrating that the trial had not strengthened the public

health care system in a sustainable way. Trial staff expressed a sense of loss at this time. Some discussed the limitations of their responsibilities to communities but others seemed to have developed a "medical imaginary", a morally charged understanding of what medicine is and what it could be (Wendland 2012b). Through this imaginary, political demands were made that health care services continue after the trial. Overall, trial staff gained a sense of how things could be otherwise through the RTS,S trial, meaning that the clinical trial made more than material impacts, it impacted people's ideas and conceptions of the future.

Chapter 5 adds to the social science literature about evidence production and collection in medical research (Adams 2016a; Biruk 2012; Crane 2013; Kachur 2011; Whyte 2011; Erikson 2012). I trace over space and time the blood and paper used in the RTS,S trial. These materials held and communicated evidence and throughout the data collection activities, they were moved, transformed, fragmented and digitized. This process exposed the material inequalities between Northern and Southern partners as trial staff extracted data from trial participants and sent this data abroad. While this critical perspective is important, I built upon Biruk's (2012) focus on the social processes of evidence collection during research to examine the roles of social relationships, care, affect and exchange in data collection. These aspects of data collection allowed trial staff to negotiate unequal relationships as middle figures. These aspects of data collection were not included in research protocols or the research findings and they remained unseen by Northern partners at GSK and MVI. People, places and practices were simplified and only a small sub-set of information was collected. This meant that social interactions and relationships, exchange, care and affect were absent from how people understood the scientific research. Yet, Northern partners and researchers do not understand that without these aspects, there would be no RTS,S trial and therefore no RTS,S vaccine.

The implications of this finding are, how can we build into research protocols a recognition of the human aspects of research? How might there be room to acknowledge the frustrations, expectations, joy, misrecognitions, anger and doubt? I observed trial staff negotiating challenging relationships and situations by using care, affect and exchange to strengthen social relationships, which enabled the trial to function. These aspects of the research were not included in the research protocols and they cannot be modeled since they are pragmatic. They also would not simply disappear if institutional arrangements were more equal. There will

always be inherent hierarchies and inequalities between people and institutions because of the nature of research, which includes a need to have people oversee activities, resources not benefiting all people equally, and some activities being more valued than others. RTS,S trial staff had to make sense of the contradictions inherent in the partnerships and clinical trial; they had to be content with its arrangement. In order to contend with the inequalities, people thought to the future when the RTS,S vaccine would be saving lives, which made their labour meaningful. Since affect, care, exchange, aspirations and social relationships are fundamental to medical research and research partnerships, they require recognition as such. This could lead to a shift in research protocols that make room for these aspects of medical research to be acknowledged, anticipated and suitably rewarded.

The aim of this thesis has been to trace the development of the RTS,S malaria vaccine as a route to explore partnerships in global health. While other anthropological studies examine institutional arrangements (Sullivan 2011; Street 2014; Brown 2015) or track research studies over years (Crane 2013), I looked at the end of global health partnerships, at a time that was laden with meaning and reflection. Conducting research at this time provided me the opportunity to gain an understanding of people as they were coming to terms with the inequalities, the impacts of the trial, and their expenditure of caring and affective labour.

What might this research mean for broader understandings of global health, international development, and medical research? How might ideas about partnership contribute to various areas within anthropology? And what might be the implications for future research about partnership?

Understanding particular global health partnerships does not allow all global health partnerships to be understood. Each partnership has its own particular configuration and generates different kinds of relationships and reflections. Nevertheless, this thesis explored diverse academic areas, including care, exchange, affect, power, materiality, medicine, labour, development, scientific knowledge production, infrastructure and technology. By having these areas of study address the topic of partnership, I have expanded the conversation to include people working in a range of places and contexts. I have also attached the concept of partnership to particular people and places, making it more tangible and specific and thus easier to approach analytically.

Although my findings are contextual and the specifics may not fit with other field sites or partnerships, my findings about infrastructure, technology, medicine,

power and exchange resonate with findings about medical research and partnerships elsewhere in Africa. And the observations I have made about the role of care and affect in medical research could be further explored in other contexts. As well, an interest in care, affect, exchange and people's aspirations can enrich anthropological understandings across various areas. I suggest that research which attends to the material, social and experiential aspects of partnership can contribute to emerging understandings of global health and medical research.

## Bibliography

- Abrahamsen, Rita. 2004. "The Power of Partnerships in Global Governance." *Third World Quarterly* 25 (8): 1453–1467.
- Adams, Vincanne, Suellen Miller, Sienna Craig, and Michael Varner. 2005. "The Challenge of Cross-Cultural Clinical Trials Research: Case Report from the Tibetan Autonomous Region, People's Republic of China." *Medical Anthropology Quarterly* 19 (3): 267–289.
- Adams, Vincanne. 2016a. *Metrics: What Counts in Global Health*. Duke University Press.
- 2016b. "What Is Critical Global Health?" *Medicine Anthropology Theory* 3 (2): 187–197.
- Ake, Claude. 2001. *Democracy and Development in Africa*. Washington, DC: Brookings Institution Press.
- Alonso, P. L., T. Teuscher, and M. Tanner. 1994. "SPf66: Research for Development or Development of Research?" *Vaccine* 12 (2): 99–101.
- Anand, Nikhil. 2011. "PRESSURE: The PoliTechnics of Water Supply in Mumbai." Cultural Anthropology 26 (4): 542–564.
- Anderson, Warwick, and Vincanne Adams. 2008. "Pramoedya's Chickens: Postcolonial Studies of Technoscience." In *The Handbook of Science and Technology Studies*, edited by Edward J Hackett, Olga Amsterdamska, Michael Lynch, and Judy Wajcman, Third, 181–204. Cambridge, Massachusetts: The MIT Press.
- Anderson, Warwick. 2009. "From Subjugated Knowledge to Conjugated Subjects: Science and Globalisation, or Postcolonial Studies of Science?" *Postcolonial Studies* 12 (4): 389–400.
- Angell, Marcia. 1997. "The Ethics of Clinical Research in the Third World." *New England Journal of Medicine* 337: 847–848.
- Appel, Hannah. 2012. "Offshore Work: Oil, Modularity, and the How of Capitalism in Equatorial Guinea." *American Ethnologist* 39 (4): 692–709.
- Ashley, Elizabeth A., Aung Pyae Phyo, and Charles J. Woodrow. 2018. "Malaria." *The Lancet* 391 (10130): 1608–21.
- Badgett, M. R., A. Auer, L. E. Carmichael, C. R. Parrish, and J. J. Bull. 2002. "Evolutionary Dynamics of Viral Attenuation." *Journal of Virology* 76 (20): 10524–10529.
- Balter, Michael. 2000. "Can WHO Roll Back Malaria?" Science, October 20.
- Bear, Laura. 2007. Lines of the Nation: Indian Railway Workers, Bureaucracy, and the Intimate Historical Self. Cultures of History. New York: Columbia University Press.
- Beck, Ann. 1977. "Medicine and Society in Tanganyika, 1890-1930; A Historical Inquiry." *Transactions of the American Philosophical Society* 67 (3): 1.
- Beisel, Uli, René Umlauf, Eleanor Hutchinson, and Clare I. R. Chandler. 2015. "The Complexities of Simple Technologies: Re-Imagining the Role of Rapid Diagnostic Tests in Malaria Control Efforts." *Malaria Journal* 15: 64.
- Biehl, João Guilherme. 2007. "Pharmaceuticalization: AIDS Treatment and Global Health Politics." *Anthropological Quarterly* 80 (4): 1083–1126.

—. 2016. "Theorizing Global Health." Medicine Anthropology Theory 3 (2): 127– 142.

Bijker, Wiebe E. 2007. "Dikes and Dams, Thick with Politics." *Isis* 98 (1): 109–123.

Binka, Fred. 2005. "Editorial: North–South Research Collaborations: A Move towards a True Partnership?" *Tropical Medicine & International Health* 10 (3): 207–209.

Birn, Anne-Emanuelle. 2014. "Philanthrocapitalism, Past and Present: The Rockefeller Foundation, the Gates Foundation, and the Setting(s) of the International/Global Health Agenda." *Hypothesis Journal* 12 (1): 1–27.

- Biruk, Crystal. 2012. "Seeing Like a Research Project: Producing 'High-Quality Data' in AIDS Research in Malawi." *Medical Anthropology* 31 (4): 347–366.
- Bovaird, Tony. 2004. "Public–Private Partnerships: From Contested Concepts to Prevalent Practice." *International Review of Administrative Sciences* 70 (2): 199–215.
- Bowker, Geoffrey C., and Susan Leigh Star. 2000. "Invisible Mediators of Action: Classification and the Ubiquity of Standards." *Mind, Culture, and Activity* 7 (1–2): 147–163.
- Brinkerhoff, Jennifer M. 2002. "Government-Nonprofit Partnership: A Defining Framework." *Public Administration and Development* 22 (1): 19–30.
- Brinkerhoff, Jennifer M., and Derick W. Brinkerhoff. 2002. "Government-Nonprofit Relations in Comparative Perspective: Evolution, Themes and New Directions." *Public Administration and Development* 22 (1): 3–18.
- Broadbent, Jane, and Richard Laughlin. 2003. "Public Private Partnerships: An Introduction." *Accounting, Auditing & Accountability Journal* 16 (3): 332–341.
- Brown, Hannah. 2015. "Global Health Partnerships, Governance, and Sovereign Responsibility in Western Kenya: Partnerships and Sovereign Responsibility." *American Ethnologist* 42 (2): 340–355.
- Brundtland, Gro Harlem. 1998. "Address to the Fifty-First World Health Assembly." Geneva: World Health Assembly.
- Buse, Kent, and Andrew Harmer. 2004. "Power to the Partners?: The Politics of Public-Private Health Partnerships." *Development* 47 (2): 49–56.
  - ——. 2007. "Seven Habits of Highly Effective Global Public–Private Health Partnerships: Practice and Potential." *Social Science & Medicine* 64 (2): 259–271.
- Buse, Kent, and Gill Walt. 2000a. "Global Public-Private Partnerships: Part I-A New Development in Health?" *Bulletin of the World Health Organization* 78 (4): 549–561.
- 2000b. "Global Public-Private Partnerships: Part II-What Are the Health Issues for Global Governance?" *Bulletin of the World Health Organization* 78 (5): 699–709.
- Bush, Ray. 2007. Poverty and Neoliberalism: Persistence and Reproduction in the Global South. London; Ann Arbor, Mich.: Pluto.
- Carsten, Janet. 2013. "Introduction: Blood Will Out." *Journal of the Royal Anthropological Institute* 19 (S1).
- Carter, Eric D. 2012. "Enemy in the Blood: Malaria, Environment, and Development in Argentina." Tuscaloosa: University of Alabama Press.

- —. 2014. "Malaria Control in the Tennessee Valley Authority: Health, Ecology, and Metanarratives of Development." *Journal of Historical Geography* 43 (Complete): 111–27.
- Casares, Sofia, Teodor-Doru Brumeanu, and Thomas L. Richie. 2010. "The RTS,S Malaria Vaccine." *Vaccine* 28 (31): 4880–4894.
- Chandler, Clare I. R., and Uli Beisel. 2017. "The Anthropology of Malaria: Locating the Social." *Medical Anthropology* 36 (5): 411–21.
- Chandler, Clare I. R., Lindsay Mangham, Abanda Ngu Njei, Olivia Achonduh, Wilfred F. Mbacham, and Virginia Wiseman. 2012. "As a Clinician, You Are Not Managing Lab Results, You Are Managing the Patient': How the Enactment of Malaria at Health Facilities in Cameroon Compares with New WHO Guidelines for the Use of Malaria Tests." Social Science & Medicine 74 (10): 1528–35.
- Chantler, Tracey, Faith Otewa, Peter Onyango, Ben Okoth, Frank Odhiambo, Michael Parker, and Paul Wenzel Geissler. 2013. "Ethical Challenges That Arise at the Community Interface of Health Research: Village Reporters' Experiences in Western Kenya." *Developing World Bioethics* 13 (1): 30–37.
- Chantler, Tracey. 2012. "Community Engagement & Ethical Practice in Vaccine Research." PhD thesis, London School of Hygiene & Tropical Medicine.
- Chataway, Joanna, and James Smith. 2006. "The International AIDS Vaccine Initiative (IAVI): Is It Getting New Science and Technology to the World?s Neglected Majority?" *World Development* 34 (1): 16–30.
- Chataway, Joanna, Rebecca Hanlin, Alessandro Rosiello, and James Smith. April 2007b. "Rethinking Vaccine R&D in Developing Countries: Introduction to This Issue." *International Journal of Technology Management & Sustainable Development* 6 (1): 3–7.
- Chataway, Joanna, Rebecca Hanlin, Julius Mugwagwa, and Lois Muraguri. 2010. "Global Health Social Technologies: Reflections on Evolving Theories and Landscapes." *Research Policy* 39 (10): 1277–1288.
- Chataway, Joanna, Stefano Brusoni, Eugenia Cacciatori, Rebecca Hanlin, and Luigi Orsenigo. 2007a. "The International AIDS Vaccine Initiative (IAVI) in a Changing Landscape of Vaccine Development: A Public/Private Partnership as Knowledge Broker and Integrator." *The European Journal of Development Research* 19 (1): 100–117.
- Clyde, David F. 1967. *Malaria in Tanzania*. Oxford Medical Publications. London: Oxford University Press.
- Coe, Andrew. 2006a. "Korogwe District in Tanga Region." https://en.wikipedia.org/wiki/Korogwe#/media/File:Korogwe.GIF
  - ——. 2006b. "Korogwe Located in Tanzania."

https://en.wikipedia.org/wiki/Korogwe#/media/File:Tanzania\_location\_map.sv

- Cohen, Joe, Sarah Benns, Johan Vekemans, Amanda Leach, and Lode Schuerman. 2011. "Development of the RTS,S/AS Vaccine Candidate from Concept to Phase III." In *Progress in Parasitology*, edited by H Melhorn, 121–133. Parasitology Research Monographs 2.
- Cohen, Joe, Victor Nussenzweig, Johan Vekemans, and Amanda Leach. 2010. "From the Circumsporozoite Protein to the RTS, S/AS Candidate Vaccine." *Human Vaccines* 6 (1): 90–96.

- Cooper, Melinda. 2008. "Experimental Labour? Offshoring Clinical Trials to China." *East Asian Science, Technology and Society: An International Journal* 2 (1): 73–92.
- Cornwall, Andrea. 2007. "Buzzwords and Fuzzwords: Deconstructing Development Discourse." *Development in Practice* 17 (4–5): 471–484.
- Crane, Johanna T. 2010. "Unequal 'Partners'. AIDS, Academia, and the Rise of Global Health." *Behemoth: A Journal on Civilisation* 03 (03): 78–97.
  - 2013. Scrambling for Africa: AIDS, Expertise, and the Rise of American Global Health Science. Ithaca: Cornell University Press.
- Crawley, Jane, Cindy Chu, George Mtove, and François Nosten. 2010. "Malaria in Children." *The Lancet* 375 (9724): 1468–1481.
- Crewe, Emma, and Elizabeth Harrison. 1998. *Whose Development?: An Ethnography of Aid*. Zed Books.
- Desowitz, Robert S. 1991. The Malaria Capers: More Tales of Parasites and People, Research and Reality. New York: W.W. Norton.
  - ——. 2002. Federal Bodysnatchers and the New Guinea Virus: Tales of Parasites, People, and Politics. W. W. Norton & Company.
- Dilger, Hansjörg. 2009. "Doing Better? Religion, the Virtue-Ethics of Development, and the Fragmentation of Health Politics in Tanzania." *Africa Today* 56 (1): 89–110.
- Doolan, D. L., C. Dobano, and J. K. Baird. 2009. "Acquired Immunity to Malaria." *Clinical Microbiology Reviews* 22 (1): 13–36.
- Eckl, Julian. 2017. "The Social Lives of Global Policies against Malaria: Conceptual Considerations, Past Experiences, and Current Issues." *Medical Anthropology* 36 (5): 422–35.
- Ecks, Stefan. 2008. "Global Pharmaceutical Markets and Corporate Citizenship: The Case of Novartis? Anti-Cancer Drug Glivec." *BioSocieties* 3 (2): 165–181.
- Ellison, James. 2014. "First-Class Health: Amenity Wards, Health Insurance, and Normalizing Health Care Inequalities in Tanzania." *Medical Anthropology Quarterly* 28 (2): 162–181.
- Emanuel, Ezekiel J., David Wendler, Jack Killen, and Christine Grady. 2004. "What Makes Clinical Research in Developing Countries Ethical? The Benchmarks of Ethical Research." *The Journal of Infectious Diseases* 189 (5): 930–937.
- Engelke, Matthew. 2008. "The Objects of Evidence." *Journal of the Royal Anthropological Institute* 14 (s1).
- Erikson, Susan L. 2012. "Global Health Business: The Production and Performativity of Statistics in Sierra Leone and Germany." *Medical Anthropology* 31 (4): 367–384.
- Escobar, Arturo. 2011. Encountering Development: The Making and Unmaking of the Third World. Princeton University Press.
- Evans, Alison, and Erasto Ngalwea. 2003. "Tanzania." *Development Policy Review* 21 (2): 271–287.
- Fabian, Johannes. 1983. Time and the Other: How Anthropology Makes Its Object. Columbia University Press.
- Fairhead, James, Melissa Leach, and Mary Small. 2006. "Public Engagement with Science? Local Understandings of a Vaccine Trial in The Gambia." *Journal of Biosocial Science* 38 (01): 103–116.

- Farmer, Paul. 2002. "Can Transnational Research Be Ethical in the Developing World?" *The Lancet* 360 (9342): 1266.
- Feierman, Steven. 1985. "Struggles for Control: The Social Roots of Health and Healing in Modern Africa." *African Studies Review* 28 (2/3): 73.
- Ferguson, James. 1994. The Anti-Politics Machine: "Development," Depoliticization, and Bureaucratic Power in Lesotho. U of Minnesota Press.
  - ——. 2005. "Seeing like an Oil Company: Space, Security, and Global Capital in Neoliberal Africa." *American Anthropologist* 107 (3): 377–382.
- Fowler, Alan. 2000. "Introduction-Beyond Partnership: Getting Real about NGO Relationships in the Aid System." *IDS Bulletin* 31 (3): 1–13.
- Franke-Fayard, Blandine, Jannik Fonager, Anneke Braks, Shahid M. Khan, and Chris J. Janse. 2010. "Sequestration and Tissue Accumulation of Human Malaria Parasites: Can We Learn Anything from Rodent Models of Malaria?" *PLOS Pathogens* 6 (9): e1001032.
- Gates, Bill. 2007. "Malaria Forum Keynote Address." Seattle, October. http://www.gatesfoundation.org/media-center/speeches/2007/10/bill-gatesmalaria-forum
- GAVI. 2017. "GAVI's Mission." http://www.gavi.org/about/mission/
- Geissler, P Wenzel, and Ann H. Kelly. 2016. "Field Station as Stage: Re-Enacting Scientific Work and Life in Amani, Tanzania." *Social Studies of Science* 46 (6): 912–937.
- Geissler, P. Wenzel, and Robert Pool. 2006. "Editorial: Popular Concerns about Medical Research Projects in Sub-Saharan Africa? A Critical Voice in Debates about Medical Research Ethics." *Tropical Medicine and International Health* 11 (7): 975–982.
- Geissler, P. Wenzel, Ann H. Kelly, Babatunde Imoukhuede, and Robert Pool. 2008. "'He is now like a brother, I can even give him some blood'-Relational Ethics and Material Exchanges in a Malaria Vaccine 'Trial Community' In The Gambia." *Social Science & Medicine* 67 (5): 696–707.
- Geissler, P. Wenzel. 2011. "'Transport to Where?': Reflections on the Problem of Value and Time À Propos an Awkward Practice in Medical Research." *Journal of Cultural Economy* 4 (1): 45–64.
- Geissler, P. Wenzel. 2012. "We Are Not paid—They Just Give Us': Liberalisation and the Longing for Biopolitical Discipline around an African HIV Prevention Trial." In *Rethinking Biomedicine and Governance in Africa: Contributions from Anthropology*, edited by P. Wenzel Geissler, Richard Rottenburg, and Julia Zenker, 197–227. Bielefeld: Transcript Verlag.
- ———. 2013. "Public Secrets in Public Health: Knowing Not to Know While Making Scientific Knowledge." American Ethnologist 40 (1): 13–34.
- ———. 2014. "The Archipelago of Public Health: Comments on the Landscape of Medical Research in the Twenty-First-Century Africa." In *Making and Unmaking Public Health in Africa: Ethnographic and Historical Perspectives*, edited by Ruth J. Prince and Rebecca Marsland, 231–255. Athens: Ohio University Press.
- 2015a. "A Life Science in Its African Para-State." In *Para-States and Medical Science: Making African Global Health*, edited by PW Geissler, 1–44. Durham: Duke University Press.

- —. 2015b. "What Future Remains? Remembering an African Place of Science." In *Para-States and Medical Science: Making African Global Health*, edited by P. Wenzel Geissler, 142–175. Durham: Duke University Press.
- Gerrets, Rene. 2010. "Globalizing International Health: The Cultural Politics of 'Partnership' in Tanzanian Malaria Control." PhD dissertation, Department of Anthropology, New York University.
- 2012b. "Governing Malaria: How an Old Scourge Troubles Precepts in Social Theory." In *Rethinking Biomedicine and Governance in Africa: Contributions from Anthropology*, edited by P. Wenzel Geissler, Richard Rottenburg, and Julia Zenker, 23–42. Bielefeld: Transcript Verlag.
- 2015. "International Health and the Proliferation of 'Partnerships': (Un)Intended Boost for State Institutions in Tanzania?" In *Para-States and Medical Science: Making African Global Health*, edited by P. Wenzel Geissler, 179–206. Durham: Duke University Press.
- Giblin, James Leonard, and Blandina Kaduma Giblin. 2005. A History of the Excluded: Making Family a Refuge from State in Twentieth-Century Tanzania. Oxford: James Currey.
- Gikonyo, Caroline, Philip Bejon, Vicki Marsh, and Sassy Molyneux. 2008. "Taking Social Relationships Seriously: Lessons Learned from the Informed Consent Practices of a Vaccine Trial on the Kenyan Coast." *Social Science & Medicine* 67 (5): 708–720.
- Green, Maia. 2000. "Public Reform and the Privatisation of Poverty: Some Institutional Determinants of Health Seeking Behaviour in Southern Tanzania." *Culture, Medicine and Psychiatry* 24 (4): 403–430.
- Greenwood, Brian, and G.A.T. Targett. 2011. "Malaria Vaccines and the New Malaria Agenda." *Clinical Microbiology and Infection* 17 (11): 1600–1607.
- Greenwood, Brian, and Ogobara K Doumbo. 2016. "Implementation of the Malaria Candidate Vaccine RTS,S/AS01." *The Lancet* 387 (10016): 318–319.
- Haines, Andy, David Sanders, Uta Lehmann, Alexander K Rowe, Joy E Lawn, Steve Jan, Damian G Walker, and Zulfiqar Bhutta. 2007. "Achieving Child Survival Goals: Potential Contribution of Community Health Workers." *The Lancet* 369 (9579): 2121–2131.
- Hanlin, Rebecca. 2008. "Partnerships for Vaccine Development: Building Capacity to Strengthen Developing Country Health and Innovation." Thesis PhD, University of Edinburgh.
- Harrington, John A. 1999. "Between the State and Civil Society: Medical Discipline in Tanzania." *The Journal of Modern African Studies* 37 (2): 207–239.
- Harvey, Penny, and Hannah Knox. 2008. "Otherwise Engaged': Culture, Deviance and the Quest for Connectivity through Road Construction." *Journal of Cultural Economy* 1 (1): 79–92.
  - ----. 2012. "The Enchantments of Infrastructure." *Mobilities* 7 (4): 521–536.
- Hausmann-Muela, Susanna, and Julian Eckl. 2015. "Re-Imagining Malaria A Platform for Reflections to Widen Horizons in Malaria Control." *Malaria Journal* 14: 180.

- Heggenhougen, Kris, and Joe Lugalla. 2005. *Social Change and Health in Tanzania*. Dar es Salaam University Press.
- Heggenhougen, Kris. 1987. *Community Health Workers: The Tanzanian Experience*. Oxford: Oxford University Press.
- Hetherington, Kregg. 2014. "Waiting for the Surveyor: Development Promises and the Temporality of Infrastructure: Waiting for the Surveyor." *The Journal of Latin American and Caribbean Anthropology* 19 (2): 195–211.
- Hoffman, Stephen L., Johan Vekemans, Thomas L. Richie, and Patrick E. Duffy. 2015. "The March Toward Malaria Vaccines." *American Journal of Preventive Medicine*, Advancing Vaccines and Immunization, 49 (6): S319– S333.
- Hoffman, Stephen L., Lucy ML Goh, Thomas C. Luke, Imogene Schneider, Thong
  P. Le, Denise L. Doolan, John Sacci, et al. 2002. "Protection of Humans against Malaria by Immunization with Radiation-Attenuated Plasmodium Falciparum Sporozoites." *Journal of Infectious Diseases* 185 (8): 1155–1164.
- Hornborg, Alf. 2008. "Machine Fetishism and the Consumer's Burden." Anthropology Today 24 (5): 4–5.
- Huckel Schneider, Carmen. 2008. "Global Public Health and International Relations: Pressing Issues – Evolving Governance." *Australian Journal of International Affairs* 62 (1): 94–106.
- Hughes, Thomas P. 1987. "The Evolution of Large Technological Systems." In *The Social Construction of Technological Systems: New Directions in the Sociology and History of Technology*, edited by Wiebe E. Bijker, Thomas Parke Hughes, and Trevor J Pinch, 51–82. London: The MIT Press.
- Hunt, Nancy Rose. 1999. A Colonial Lexicon of Birth Ritual, Medicalization, and Mobility in the Congo. Ann Arbor, Michigan: Duke University Press.
- IAVI. 2008. AIDS Vaccine Blueprint 2008: A Challenge to the Field, A Roadmap for Progress. International AIDS Vaccine Initiative.
- IHI. 2016. "About the Ifakara Health Institute (IHI)." *Ifakara Health Institute*. http://ihi.or.tz/about/
- lliffe, John. 1979. *A Modern History of Tanganyika*. Cambridge: Cambridge University Press.
- ———. 1998. *East African Doctors: A History of the Modern Profession*. African Studies Series; 95. Cambridge: Cambridge University Press.
- Iskander, Dalia. 2015. "Re-Imaging Malaria in the Philippines: How Photovoice Can Help to Re-Imagine Malaria." *Malaria Journal* 14 (1): 257–69.
- Jennings, Michael. 2002. "Almost an Oxfam in Itself': Oxfam, Ujamaa and Development in Tanzania." *African Affairs* 101 (405): 509–530.
- Jentsch, Birgit, and Catherine Pilley. 2003. "Research Relationships between the South and the North: Cinderella and the Ugly Sisters?" *Social Science & Medicine* 57 (10): 1957–1967.
- Kachur, S Patrick. 2011. "The Plausibility Design, Quasi-Experiments and Real-World Research: A Case Study of Antimalarial Combination Treatment in Tanzania." In *Evidence, Ethos and Experiment: The Anthropology and History of Medical Research in Africa*, edited by P. Wenzel Geissler and Catherine Molyneux, 197–227. Oxford: Berghahn Books.
- Kahabuka, Catherine, Gunnar Kvåle, and Sven Gudmund Hinderaker. 2012. "Factors Associated with Severe Disease from Malaria, Pneumonia and

Diarrhea among Children in Rural Tanzania–A Hospital-Based Cross-Sectional Study." *BMC Infectious Diseases* 12 (1): 219.

- Kale, Dinar, Rebecca Hanlin, and Joanna Chataway. 2013. "New Drugs and Health Technologies for Low-Income Populations: Will the Private Sector Meet the Needs of Low-Income Populations in Developing Countries?" *Innovation and Development* 3 (1): 121–137.
- Kamat, Vinay R. 2006. "I Thought It Was Only Ordinary Fever!' Cultural Knowledge and the Micropolitics of Therapy Seeking for Childhood Febrile Illness in Tanzania." *Social Science & Medicine* 62 (12): 2945–59.
- ———. 2009. "Cultural Interpretations of the Efficacy and Side Effects of Antimalarials in Tanzania." *Anthropology & Medicine* 16 (3): 293–305.
- ———. 2013. Silent Violence: Global Health, Malaria, and Child Survival in Tanzania. Tucson, AZ: University of Arizona Press.
- Kamat, Vinay R., and Daniel J. Nyato. 2010. "Soft Targets or Partners in Health? Retail Pharmacies and Their Role in Tanzania's Malaria Control Program." Social Science & Medicine 71 (3): 626–33.
- Kelly, Ann H. 2011. "Remembering Bambali: Evidence, Ethics and the Co-Production of Truth." In *Evidence, Ethos, Experiments*, edited by P. Wenzel Geissler and Catherine Molyneux, 229–244. Oxford: Berghahn Books.
  - ——. 2012. "Serving the City: Community-Based Malaria Control in Dar Es Salaam." In *Rethinking Biomedicine and Governance in Africa*, edited by PW Geissler, Richard Rottenburg, and Julia Zenker, 161–76. Bielefeld: Transcript Verlag.
- Kelly, Ann H., David Ameh, Silas Majambere, Steve Lindsay, and Margaret Pinder. 2010. "'Like Sugar and Honey': The Embedded Ethics of a Larval Control Project in The Gambia." *Social Science & Medicine* 70 (12): 1912–1919.
- Kelly, Ann H., Hermione N. Boko Koudakossi, and Sarah J. Moore. 2017.
  "Repellents and New 'Spaces of Concern' in Global Health." *Medical Anthropology* 36 (5): 464–78.
- Kelly, Ann H., and Javier Lezaun. 2014. "Urban Mosquitoes, Situational Publics, and the Pursuit of Interspecies Separation in Dar Es Salaam." *American Ethnologist* 41 (2): 368–83.
- Kelly, Ann H., and P. Wenzel Geissler. 2011. "Introduction: The Value of Transnational Medical Research." *Journal of Cultural Economy* 4 (1): 3–10.
- Kelly, Ann H., and Uli Beisel. 2011. "Neglected Malarias: The Frontlines and Back Alleys of Global Health." *BioSocieties* 6 (1): 71–87.
- Khatib, Rashid A, Gerry F Killeen, Salim MK Abdulla, Elizeus Kahigwa, Peter D McElroy, Rene PM Gerrets, Hassan Mshinda, Alex Mwita, and S Patrick Kachur. 2008. "Markets, Voucher Subsidies and Free Nets Combine to Achieve High Bed Net Coverage in Rural Tanzania." *Malaria Journal* 7 (1): 98.
- Kimaro, Didas, Balthazar M. Msanya, and Yasuo Takamura. 1994. "Review of Sisal Production and Research in Tanzania."
- Knauft, Bruce M. 1999. *From Primitive to Postcolonial in Melanesia and Anthropology*. Ann Arbor, Michigan: University of Michigan Press.
- Lambert, Helen. 2009. "Evidentiary Truths? The Evidence of Anthropology through the Anthropology of Medical Evidence." *Anthropology Today* 25 (1): 16–20.

- Langwick, Stacey A. 2008. "Articulate(d) Bodies: Traditional Medicine in a Tanzanian Hospital." *American Ethnologist* 35 (3): 428–39.
- Larkin, Brian. 2013. "The Politics and Poetics of Infrastructure." *Annual Review of Anthropology* 42 (1): 327–343.
- Latour, Bruno. 1996. Aramis, Or, The Love of Technology. Harvard University Press.
  2000. "When Things Strike Back: A Possible Contribution of 'Science Studies' to the Social Sciences." The British Journal of Sociology 51 (1): 107–123.
- Leach, Melissa, and James Fairhead. 2011. "Being 'with the Medical Research Council': Infant Care and the Meanings of Cohort Membership in Gambia's Plural Therapeutic Landscapes." In *Evidence, Ethos and Experiments*, edited by P. Wenzel Geissler and Catherine Molyneux. Oxford: Berghahn Books.
- Lee, Sujin, and Minh Trang Nguyen. 2015. "Recent Advances of Vaccine Adjuvants for Infectious Diseases." *Immune Network* 15 (2): 51–57.
- Li, Tania Murray. 1999. "Compromising Power: Development, Culture, and Rule in Indonesia." *Cultural Anthropology* 14 (3): 295–322.
- Litsios, Socrates. 2015. "Re-Imagining the Control of Malaria in Tropical Africa During the Early Years of the World Health Organization." *Malaria Journal* 14: 178.
- Mackinnon, MJ, and K. Marsh. 2010. "The Selection Landscape of Malaria Parasites." *Science* 328 (5980): 866–71.
- Mahende, Coline, Billy Ngasala, John Lusingu, Allvan Butichi, Paminus Lushino, Martha Lemnge, and Zul Premji. 2014. "Aetiology of Acute Febrile Episodes in Children Attending Korogwe District Hospital in North-Eastern Tanzania." Edited by Ana Paula Arez. *PLoS ONE* 9 (8): e104197.

Malinowski, Bronislaw. 2014 [1922]. Argonauts of the Western Pacific. Routledge.

Mandike, Renata. 2013. "Recent Developments and Achievements in Malaria Control in Tanzania (Mainland)." presented at the National Malaria Control Program (NMCP), Dar es Salaam. http://www.tzdpg.or.tz/fileadmin/documents/dpg\_internal/dpg\_working\_group

s\_clusters/cluster\_2/health/DPGH\_Meeting\_Documents\_2011/National\_Mal aria\_Control\_Program-Tanzania\_Mainland.pdf.

- Manzi, Fatuma, Joanna Armstrong Schellenberg, Guy Hutton, Kaspar Wyss, Conrad Mbuya, Kizito Shirima, Hassan Mshinda, Marcel Tanner, and David Schellenberg. 2012. "Human Resources for Health Care Delivery in Tanzania: A Multifaceted Problem." *Human Resources for Health* 10: 3.
- Marcis, FL. 2015. "Life Promises and 'Failed' Family Ties: Expectations and Disappointment within a Clinical Trial (Ivory Coast)." *Anthropology & Medicine* 22 (3): 295–308.
- Marcus, George E. 1995. "Ethnography In/Of the World System: The Emergence of Multi-Sited Ethnography." *Annual Review of Anthropology* 24: 95–117.
- Marsland, Rebecca. 2005. "Ethnographic Malaria: The Uses of Medical Knowledge in Tanzania." School of Oriental and African Studies, University of London.
- Mauss, Marcel. 2011 [1925]. The Gift: Forms and Functions of Exchange in Archaic Societies. Martino Publishing.
- Maxmen, Amy. 2015. "Parasite Mismatch Explains Mediocre Performance of Leading Malaria Vaccine." *Nature News*, October.

- Maxwell, Simon, and Roger Riddell. 1998. "Conditionality or Contract: Perspectives on Partnership for Development." *Journal of International Development* 10 (2): 257–268.
- McGoey, Linsey, Julian Reiss, and Ayo Wahlberg. 2011. "The Global Health Complex." *BioSocieties* 6 (1): 1.
- McGoey, Linsey. 2012. "Philanthrocapitalism and Its Critics." *Poetics* 40 (2): 185–199.

— 2015. No Such Thing as a Free Gift: The Gates Foundation and the Price of Philanthropy. London: Verso.

- Mitchell, Timothy. 2002. *Rule of Experts: Egypt, Techno-Politics, Modernity*. Berkeley: University of California Press.
- Mmbando, Bruno P., Lasse S. Vestergaard, Andrew Y. Kitua, Martha M. Lemnge, Thor G. Theander, and John PA Lusingu. 2010. "A Progressive Declining in the Burden of Malaria in North-Eastern Tanzania." *Malaria Journal* 9 (1): 216.
- Molyneux, Sassy, and P. Wenzel Geissler. 2008. "Ethics and the Ethnography of Medical Research in Africa." *Social Science & Medicine*, Part Special Issue: Ethics and the Ethnography of Medical Research in Africa, 67 (5): 685–695.
- Molyneux, Sassy, Dorcas Kamuya, Philister Adhiambo Madiega, Tracey Chantler, Vibian Angwenyi, and P. Wenzel Geissler. 2013. "Field Workers at the Interface: Editorial." *Developing World Bioethics* 13 (1): ii–iv.
- Montgomery, Catherine C., Khatia Munguambe, and Robert Pool. 2010. "Group-Based Citizenship in the Acceptance of Indoor Residual Spraying (IRS) for Malaria Control in Mozambique" *Social Science & Medicine* 70: 1648–55.
- Moorthy, Vasee S, and Jean-Marie Okwo-Bele. 2015. "Final Results from a Pivotal Phase 3 Malaria Vaccine Trial." *The Lancet* 386 (9988): 5–7.
- Mosse, David. 2005. *Cultivating Development: An Ethnography of Aid Policy and Practice*. Anthropology, Culture, and Society. London: Pluto Press.
- Mubi, Marycelina, Annika Janson, Marian Warsame, Andreas Mårtensson, Karin Källander, Max G. Petzold, Billy Ngasala, et al. 2011. "Malaria Rapid Testing by Community Health Workers Is Effective and Safe for Targeting Malaria Treatment: Randomised Cross-Over Trial in Tanzania." Edited by François Nosten. *PLoS ONE* 6 (7): e19753.
- Muraskin, William. 2004. "The Global Alliance for Vaccines and Immunization: Is It a New Model for Effective Public--Private Cooperation in International Public Health?" *The American Journal of Public Health* 94 (11): 1922–1926.
- MVI-GSK. 2015. RTS,S Frequently Asked Questions (FAQs). http://www.malariavaccine.org/files/MVI-GSK-FAQ-FINAL-web.pdf
- Nading, Alex M. 2015. "Chimeric Globalism: Global Health in the Shadow of the Dengue Vaccine: Chimeric Globalism." *American Ethnologist* 42 (2): 356–370.
- Napier, Steve. 2017. "A Danish Architect in Africa." *Cardigan Row.* http://cardiganrow.com/architecture/danish-architect-africa
- National Bureau of Statistics. 2012. *Population and Housing Census*. Dar es Salaam: Tanzanian Ministry of Finance. https://www.meac.go.tz/sites/default/files/Statistics/Tanzania%20Population %20Census%202012.pdf
- Neafsey, Daniel E., Michal Juraska, Trevor Bedford, David Benkeser, Clarissa Valim, Allison Griggs, Marc Lievens, et al. 2015. "Genetic Diversity and

Protective Efficacy of the RTS,S/AS01 Malaria Vaccine." *New England Journal of Medicine* 373 (21): 2025–2037.

- Nguyen, Vinh-Kim. 2005. "Antiretroviral Globalism, Biopolitics, and Therapeutic Citizenship." In *Global Assemblages: Technology, Politics, and Ethics as Anthropological Problems*, edited by Aihwa Ong and Stephen J. Collier, 124– 144. Oxford: Blackwell Publishing Ltd.
- ———. 2009. "Government-by-Exception: Enrolment and Experimentality in Mass HIV Treatment Programmes in Africa." Social Theory & Health 7 (3): 196– 217.
- ———. 2015. "Treating to Prevent HIV: Population Trials and Experimental Societies." In *Para-States and Medical Science: Making African Global Health*, edited by P. Wenzel Geissler, 47–77. Durham: Duke University Press.
- NIH. 2008. Understanding Vaccines: What They Are, How They Work. National Institutes for Health.
- NIMR. 2017. "Tanga Research Centre—NIMR Tanzania." *NIMR National Institute for Medical Research*. https://www.nimr.or.tz/research-centres/tanga-research-centre/
- Nyerere, Julius K. 1968. *Ujamaa: Essays on Socialism*. London: Oxford University Press.
- Nyika, Aceme, Roma Chilengi, Deus Ishengoma, Sally Mtenga, Mahamadou A. Thera, Mahamadou S. Sissoko, John Lusingu, et al. 2010. "Engaging Diverse Communities Participating in Clinical Trials: Case Examples from across Africa." *Malaria Journal* 9 (1): 86.
- Okwaro, Ferdinand, and P. Wenzel Geissler. 2015. "In/Dependent Collaborations: Perceptions and Experiences of African Scientists in Transnational HIV Research." *Medical Anthropology Quarterly* 29 (4): 492–511.
- Olotu, Ally, John Lusingu, Amanda Leach, Marc Lievens, Johan Vekemans, Salum Msham, Trudie Lang, et al. 2011. "Efficacy of RTS, S/AS01E Malaria Vaccine and Exploratory Analysis on Anti-Circumsporozoite Antibody Titres and Protection in Children Aged 5–17 Months in Kenya and Tanzania: A Randomised Controlled Trial." *The Lancet Infectious Diseases* 11 (2): 102– 109.
- O'Neill, Sarah, Charlotte Gryseels, Susan Dierickx, Julia Mwesigwa, Joseph Okebe, Umberto d'Alessandro, and Koen Peeters Grietens. 2015. "Foul Wind, Spirits and Witchcraft: Illness Conceptions and Health-Seeking Behaviour for Malaria in the Gambia." *Malaria Journal* 14 (April): 167.
- Packard, Randall M. 1997. "Malaria Dreams: Postwar Visions of Health and Development in the Third World." *Medical Anthropology* 17 (3): 279–96.
- ———. 2007. *The Making of a Tropical Disease: A Short History of Malaria*. Baltimore, Md.: The Johns Hopkins University Press.
- ------. 2016. A History of Global Health: Interventions into the Lives of Other Peoples. Baltimore, Md.: Johns Hopkins University Press.
- Packard, Randall M., and Peter J. Brown. 1997. "Rethinking Health, Development, and Malaria: Historicizing a Cultural Model in International Health." *Medical Anthropology* 17 (3): 181–94.
- PATH-MVI. 2016. "Fact Sheet: RTS,S Malaria Vaccine Candidate (Mosquirix<sup>™</sup>)." http://www.malariavaccine.org/sites/www.malariavaccine.org/files/content/pa ge/files/RTSS%20vaccine%20candidate%20Factsheet\_FINAL.pdf

- Penny, Melissa A, Robert Verity, Caitlin A Bever, Christophe Sauboin, Katya Galactionova, Stefan Flasche, Michael T White, et al. 2016. "Public Health Impact and Cost-Effectiveness of the RTS,S/AS01 Malaria Vaccine: A Systematic Comparison of Predictions from Four Mathematical Models." *The Lancet* 387 (10016): 367–375.
- Petryna, Adriana. 2005. "Ethical Variability: Drug Development and Globalizing Clinical Trials." *American Ethnologist* 32 (2): 183–197.
  - ——. 2009. When Experiments Travel: Clinical Trials and the Global Search for Human Subjects. Princeton University Press.
- President's Malaria Initiative (PMI). 2013. "Malaria Operational Plan FY 2013: Tanzania." https://www.pmi.gov/docs/default-source/default-documentlibrary/malaria-operational-plans/fy13/tanzania\_mop\_fy13.pdf?sfvrsn=8.
- Ranson, Hilary, Raphael N'guessan, Jonathan Lines, Nicolas Moiroux, Zinga Nkuni, and Vincent Corbel. 2011. "Pyrethroid Resistance in African Anopheline Mosquitoes: What Are the Implications for Malaria Control?" *Trends in Parasitology* 27 (2): 91–98.
- Ravishankar, Nirmala, Paul Gubbins, Rebecca J. Cooley, Katherine Leach-Kemon, Catherine M. Michaud, Dean T. Jamison, and Christopher JL Murray. 2009. "Financing of Global Health: Tracking Development Assistance for Health from 1990 to 2007." *The Lancet* 373 (9681): 2113–2124.
- Richie, Thomas L., Peter F. Billingsley, B. Kim Lee Sim, Eric R. James, Sumana Chakravarty, Judith E. Epstein, Kirsten E. Lyke, et al. 2015. "Progress with Plasmodium Falciparum Sporozoite (PfSPZ)-Based Malaria Vaccines." *Vaccine* 33 (52): 7452–7461.
- Richter, Judith. 2004. "Public-Private Partnerships for Health: A Trend with No Alternatives?" *Development* 47 (2): 43–48.
- Rocco, Fiammetta. 2003. Quinine: Malaria and the Quest for a Cure That Changed the World. New York, NY: HarperCollins.
- Rottenburg, Richard. 2009. "Social and Public Experiments and New Figurations of Science and Politics in Postcolonial Africa1." *Postcolonial Studies* 12 (4): 423–440.
- RTS,S Clinical Trials Partnership. 2015. "Efficacy and Safety of RTS,S/AS01 Malaria Vaccine with or without a Booster Dose in Infants and Children in Africa: Final Results of a Phase 3, Individually Randomised, Controlled Trial." *The Lancet* 386 (9988): 31–45.
- Sariola, Salla, and Bob Simpson. 2011. "Theorising the 'Human Subject?' in Biomedical Research: International Clinical Trials and Bioethics Discourses in Contemporary Sri Lanka." *Social Science & Medicine* 73 (4): 515–521.
- Scott, James C. 1998. Seeing like a State: How Certain Schemes to Improve the Human Condition Have Failed. New Haven, Conn.: Yale University Press.
- Seder, Robert A., Lee-Jah Chang, Mary E. Enama, Kathryn L. Zephir, Uzma N. Sarwar, Ingelise J. Gordon, LaSonji A. Holman, et al. 2013. "Protection Against Malaria by Intravenous Immunization with a Nonreplicating Sporozoite Vaccine." Science 341 (6152): 1359–1365.
- Shabani, Ibrahim, Martin E. Kimanya, Peter N. Gichuhi, Conrad Bonsi, and Adelia C. Bovell-Benjamin. 2015. "Maize Storage and Consumption Practices of Farmers in Handeni District, Tanzania: Corollaries for Mycotoxin Contamination." *Open Journal of Preventive Medicine* 05 (08): 330–339.

- Shah, Sonia. 2010. The Fever: How Malaria Has Ruled Humankind for 500,000 Years. Farrar, Straus and Giroux.
- Sherman, Irwin W. 2009. *The Elusive Malaria Vaccine: Miracle or Mirage?* Washington, DC: ASM Press.
- Shiner, Alice. 2003. "Shaping Health Care in Tanzania—Who's Pulling the Strings?" Lancet 362: 829–830.
- Shum, Ting Ting. 2010. "Slipping Through the Holes: Nets and Networks, Malaria and Marginality in Southeast Tanzania." Maynooth: National University of Ireland.
- Simpson, Bob, and Salla Sariola. 2012. "Blinding Authority." *Science, Technology, & Human Values* 37 (5): 555–575.
- Star, Susan Leigh, and Karen Ruhleder. 1996. "Steps toward an Ecology of Infrastructure: Design and Access for Large Information Spaces." *Information Systems Research* 7 (1): 111–134.
- Star, Susan Leigh. 1999. "The Ethnography of Infrastructure." *American Behavioral Scientist* 43 (3): 377–391.
- Storeng, Katerini T. 2014. "The GAVI Alliance and the 'Gates Approach?' to Health System Strengthening." *Global Public Health* 9 (8): 865–879.
- Strathern, Marilyn. 1988. The Gender of the Gift: Problems with Women and Problems with Society in Melanesia. University of California Press.
  - ——. 2011. "Can One Rely on Knowledge?" In Evidence, Ethos and Experiments: The Anthropology and History of Medical Research in Africa, edited by P. Wenzel Geissler and Catherine Molyneux, 57–75. Oxford: Berghahn Books.
- Street, Alice. 2014. Biomedicine in an Unstable Place: Infrastructure and Personhood in a Papua New Guinean Hospital. Experimental Futures. Durham: Duke University Press.
- ———. 2016. "The Hospital and the Hospital: Infrastructure, Human Tissue, Labour and the Scientific Production of Relational Value." *Social Studies of Science* 46 (6): 938–960.
- Sullivan, Noelle. 2011. "Mediating Abundance and Scarcity: Implementing an HIV/AIDS-Targeted Project Within a Government Hospital in Tanzania." *Medical Anthropology* 30 (2): 202–221.
- Sunder Rajan, Kaushik. 2006. *Biocapital: The Constitution of Postgenomic Life*. Duke University Press.
  - . 2007. "Experimental Values." New Left Review, II, no. 45: 67–88.
- Tanner, Marcel. 2017. "Malaria Vaccines." *Swiss Tropical Public Health TPH*. https://www.swisstph.ch/en/about/eph/health-interventions/malaria-vaccines/
- The Global Fund to Fight, and AIDS, Tuberculosis and Malaria. 2016. *Results Report 2016 - The Global Fund to Fight AIDS, Tuberculosis and Malaria*. https://www.theglobalfund.org/media/1122/corporate\_2016resultsreport\_report\_report\_en.pdf
- THMIS. 2013. *Tanzania HIV/AIDS and Malaria Indicator Survey*. National Bureau of Statistics (NBS). https://dhsprogram.com/pubs/pdf/AIS11/AIS11.pdf
- Timmermans, Stefan, and Marc Berg. 2003. The Gold Standard: The Challenge of Evidence-Based Medicine and Standardization in Health Care. Philadelphia, Pa: Temple University Press.
- Tichenor, Marlee. 2017. "Data Performativity, Performing Health Work: Malaria and Labor in Senegal." *Medical Anthropology* 36 (5): 436–48.

- Tousignant, Noemi. 2013. "Broken Tempos: Of Means and Memory in a Senegalese University Laboratory." *Social Studies of Science* 43 (5): 729–753.
- Trampuz, Andrej, Matjaz Jereb, Igor Muzlovic, and Rajesh M Prabhu. 2003. "Clinical Review: Severe Malaria." *Critical Care* 7 (4): 315–323.
- Turnbull, David. 1989. "The Push for a Malaria Vaccine." *Social Studies of Science* 19 (2).
- Turshen, Meredeth. 1984. *The Political Ecology of Disease in Tanzania*. New Brunswick, N.J.: Rutgers University Press.
- UNITAID. 2017. "About Us." UNITAID. https://www.unitaid.eu/about-us/
- Umlauf, René. 2017. "Precarity and Preparedness: Non-Adherence as Institutional Work in Diagnosing and Treating Malaria in Uganda." *Medical Anthropology* 36 (5): 449–63.
- Vaughan, Megan. 1991. *Curing Their Ills: Colonial Power and African Illness*. Stanford, Calif.: Stanford University Press.
- Vekemans, Johan, Amanda Leach, and Joe Cohen. 2009. "Development of the RTS,S/AS Malaria Candidate Vaccine." *Vaccine* 27: G67–G71.
- Wendland, Claire. 2012a. "Animating Biomedicine's Moral Order: The Crisis of Practice in Malawian Medical Training." *Current Anthropology* 53 (6): 755– 788.
- ——. 2012b. "Moral Maps and Medical Imaginaries: Clinical Tourism at Malawi's College of Medicine." *American Anthropologist* 114 (1): 108–122.
- West, Paige. 2006. Conservation Is Our Government Now: The Politics of Ecology in Papua New Guinea. Duke University Press.
- Wheeler, Craig, and Seth Berkley. 2001. "Initial Lessons from Public-Private Partnerships in Drug and Vaccine Development." *Bulletin of the World Health Organization* 79 (8): 728–734.
- WHO. 2009. WHO Country Cooperation Strategy 2010-2015: Tanzania. World Health Organization. Regional Office for Africa. http://www.who.int/iris/handle/10665/182737
- ------. 2015a. *Country Statistics-Tanzania*. Country Statistics. World Health Organization. http://www.who.int/countries/tza/en/
- ------. 2015b. Country Statistics-United Kingdom. Country Statistics. World Health Organization. http://www.who.int/countries/gbr/en/
- ———. 2016a. Global Malaria Vaccine Pipeline Global Portfolio. http://www.who.int/immunization/research/development/Global\_malaria\_vacc ine\_pipeline\_2015Sep.pdf?ua=1
- ——. 2016b. *Malaria Vaccine: WHO Position Paper*. http://www.who.int/wer/2016/wer9104.pdf?ua=1
- ———. 2017a. "The Expanded Programme on Immunization." WHO. http://www.who.int/immunization/programmes\_systems/supply\_chain/benefit s\_of\_immunization/en/
- ------. 2017b. Update on RTS,S Malaria Vaccine Implementation Programme. World Health Organization. http://www.who.int/malaria/mpac/mpac-mar2017rtss-update-session2.pdf?ua=1
- \_\_\_\_\_. 2018. Malaria. http://www.who.int/malaria/en/
- Whyte, Susan Reynolds. 2011. "Writing Knowledge and Acknowledgement: Possibilities in Medical Research." In *Evidence, Ethos and Experiments: The*

*Anthropology and History of Medical Research in Africa*, edited by P. Wenzel Geissler and Catherine Molyneux, 29–56. Oxford: Berghahn Books.

- Widdus, Roy. 2005. "Public-Private Partnerships: An Overview." *Transactions of the Royal Society of Tropical Medicine and Hygiene* 99: 1–8.
- World Vision. 2015. *Tanzania's Community Health Workers*. World Vision-Health and Nutrition.

http://www.wvi.org/sites/default/files/CHW%20Profile%20Tanzania\_0.pdf

- WRAIR. 2011. "WRAIR: RTS,S and Malaria Vaccine Research: A Historic and Bibliometric Analysis." Silver Springs, Maryland, October 18. http://www.wrair.army.mil/Documents/Library/RTS,S%20RESEARCH.pdf
- ———. 2017. "About Us Walter Reed National Military Medical Center." Walter Reed National Military Medical Centre. http://www.wrnmmc.capmed.mil/About%20Us/SitePages/Home.aspx