



Malawi-Carolina Summer Public Health Institute

Experiences with Study Initiation and Database Creation in Blantyre and Lilongwe

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Introduction

I traveled to Malawi in the summer of 2007 to participate in the Malawi-Carolina Summer Public Health Institute funded by the UNC Office of Global Health. The five weeks that I spent in Malawi were split between Blantyre and Lilongwe. My time in Blantyre was spent participating in the week-long Health Economics Evaluation Module and then working on site selection and study logistics for an R01 focusing on the effects of HIV on neurodevelopment in young children. My two weeks in Lilongwe were spent creating a database for capture of the adverse events from the large, ongoing Breastfeeding, Antiretrovirals and Nutrition (BAN) study. I also worked on data entry and trained a Malawian study employee to continue data entry.



College of Medicine, Blantyre



Rural Clinic in Mulanje



Kamuzu Central Hospital, Lilongwe

Internship in Blantyre

Site Selection and Study Logistics. The research study I was working on in Malawi was an R01 entitled *Pediatric HIV-Encephalopathy in Malawi, Effect of ART and Role of Compartmentalization*. This study is a prospective, observational, community-based cohort study to (1) estimate the incidence of HIV associated neurological manifestations, describe their timing and determine the predictive factors in children age zero to 30 months residing in a resource-limited setting, and (2) to estimate the change in CNS manifestations following initiation of antiretroviral treatment in these children, describe their timing and determine the predictive factors associated with improvement of neurological manifestations upon initiation of ART. The PI on the study, Dr. Annelies Van Rie, was in Blantyre for a week and I worked with her to lay the foundation that would enable the study to begin recruitment later this year. Listed below are a few of my experiences working on this project while in Blantyre.

•Identification of collaborators. It was necessary to identify a Malawian pediatrician who could be a PI on the study and could help to oversee the study as well as a laboratory that could be used for sample testing. Dr. Van Rie identified the Malawi-Liverpool-Wellcome Trust (MLW) as an appropriate collaborating organization with adequate laboratory facilities and infrastructure. We met with representatives from MLW and went over the existing study protocol to assess where there was a need for changes in study procedures due to the specific resources and challenges of working in this setting.

•Site Selection. It was necessary to determine which local clinics would be used as study sites. In order to determine this we traveled to potential clinics and met with the managers and staff. We asked questions regarding patient population, drug supply, clinic capabilities, record keeping, study staff and other research studies taking place in the clinic. This was important to ensure that we could meet our recruitment goals for the study and carry out all study procedures at the sites. After visiting three sites, two sites were chosen and are set to start recruitment in December of 2007.

•Integration with current country health procedures. In order to understand the current testing, treatment, and care procedures for our study population, we spent time at the Queen Elizabeth Central Hospital (QECH) working with a pediatrician who treated HIV-exposed and infected children. This enabled us to better understand the current country guidelines on HIV testing and treatment for children, the prevention of mother to child transmission (PMTCT) programs, and the challenges faced in these areas.

Internship in Lilongwe

The Breastfeeding, Antiretrovirals and Nutrition (BAN) study is an ongoing study which began enrollment in 2004. The study is conducted at Bottom Hospital in Lilongwe. The study is a comparative clinical trial among HIV-infected women and their infants to determine (1) the benefit of nutritional supplementation given to women during breastfeeding, (2) the benefit and safety of antiretroviral medications given either to infants or to their mothers to prevent HIV transmission during breastfeeding and (3) the feasibility of exclusive breastfeeding followed by early, rapid breastfeeding cessation. The study will enroll a total of 2,418 HIV-infected women (during pregnancy) and follows the women and their babies for approximately 1 year after birth. While the majority of study documents are teleforms which are scanned in to a database on a regular schedule, the adverse events for this study were being recorded in hand-written logs. In order for this data to be used the logs needed to be captured in an electronic database. While I was in Lilongwe I worked on creating a Microsoft Access database from the source documents to capture all adverse events. I performed data entry of some of the patient files and I also trained a Malawian researcher on the database and data entry so that she could continue with the work.



Employees in the Data Department of the BAN study, Bottom Hospital, Lilongwe