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**Author Contributions:** CGN served as a Co-Principal Investigator, designed the methods for morbidity data collection and quality control as well as data coding and analysis and writing of the paper. WN and AS initially supervised data collection in the field and served as Kenyan co-investigators. ND assisted in data coding, conducted literature review, and helped to draft and edit the paper. GS assisted in data coding, conducted statistical analyses, assisted in drafting paper. GE was the Kenyan Co-Principal Investigator for the overall study. JAE served as Principal Investigator for the overall study.

## **Introduction**

In 2011, an estimated 34 million people globally were living with HIV, with 1.8 million dying from HIV-related causes and only 6.6 million receiving antiretroviral treatment (ART) (Joint United Nations Programme on HIV/AIDS, 2011). In 2012 the overall HIV prevalence in Kenya was estimated at 5.6% among 15-49 year old men and women (Kenya National AIDS Control Council, 2014). In the Uasin Gishu district of Kenya, the site of this study, the estimated HIV prevalence among adults in 2012 was 4.9% (Kenya National AIDS Control Council, 2014). In rural Kenya, as in many settings in sub-Saharan Africa, health care is not always readily available and services are fragmented (Kirigia & Barry, 2008; World Health Organization Regional Office for Africa, 2008; Adwok, Kearns, & Nyary, 2013). Access to ART remains limited, particularly for those living in rural Africa (van Dijk et al., 2009; Cooke, Tanser, Barnighausen, & Newell, 2010; Van Rompaey, Kimfuta, Kimbondi, Monn, & Buve, 2011; World Health Organization, 2014). Results from the 2012 Kenya AIDS Indicator Survey show that ART coverage for eligible HIV-infected adults and adolescents was 45.9% (according to WHO 2013 guidelines) (National AIDS and STI Control Programme Kenya, 2014).

Research in Canada, the United States, and Haiti has demonstrated that early ART can reduce morbidity, mortality, and HIV transmission (Kitahata et al., 2009; Severe et al., 2010; Cohen et al., 2011; Grinsztejn et al., 2014). Treatment with ART can also increase the ability of individuals living with HIV to carry out activities of daily living and work duties (Crystal & Sambamoorthi, 1996; Rosen, Ketlhapile, Sanne, & Desilva, 2008; Thirumurthy et al., 2011).

Previous international guidelines for starting ART utilized CD4 cut-off levels; however, current WHO guidelines recommend initiation of ART for everyone living with HIV regardless of the CD4 cell count (World Health Organization, 2015). In Kenya, particularly in rural areas where medical care and treatment for infections is often not readily available, guidelines that utilized CD4 count levels were problematic for individuals without access to follow-up care and laboratory facilities to measure CD4 counts to guide their management and treatment.

Morbidity in women who are HIV-positive may impact their quality of life and ability to care for themselves and their families (Crystal & Sambamoorthi, 1996; Rosen et al., 2008; Bignami-Van Assche, Assche, Anglewicz, & van de Ruit, 2011; Thirumurthy et al., 2011; Biraguma & Rhoda, 2012). Morbidity in women who are HIV-positive and drug-naïve has not been well described. Few studies that report morbidity outcomes in these individuals describe data by gender, and reported morbidity signs and symptoms may be nonspecific. In studies conducted in Sub-Saharan Africa before the early 2000s most individuals who were HIV-positive were likely to have been drug-naïve, given that in 2003 ART coverage in Sub-Saharan Africa was only about two percent (World Health Organization, 2014).

Malnutrition is an important factor contributing to morbidity and poor quality of life. Malnutrition diminishes the ability of the immune system to prevent and respond to infection, and it effects quality of life, resulting in fatigue, being bedridden, and lack of energy to carry out the tasks of daily living (Bain et al., 2013 ; Bresnahan & Tanumihardjo, 2014). One study of eleven countries, including Kenya, estimated a 10% prevalence of HIV-related malnutrition in women living with HIV, with increased prevalence of malnutrition in rural areas and in women with less education (Uthman, 2008). Vitamin A deficiency is strongly associated with HIV infection and disease progression (Baeten et al., 2002). Zinc deficiency also impairs immune function (Keen & Gershwin, 1990; Shankar & Prasad, 1998). Anaemia reduces endurance and capacity to perform physical work (Haas & Brownlie, 2001). Anaemia has been documented in women of childbearing age in western Kenya (Akwale et al., 2004).

Infections, such as tuberculosis (TB), malaria, bacteraemia, and fungal infections, along with malnutrition are main causes of morbidity and mortality among drug-naïve individuals living with HIV in Africa (Brindle et al., 1993; Lucas et al., 1993; Grant et al., 1997; Anglaret et al.,

1999; Freedberg, 2003; Ole-Nguyaine et al., 2004; Holmes, Losina, Walensky, Yazdanpanah, & Iwuji et al., 2011; Anglaret et al., 2012). Gastroenteritis and chronic diarrhoea have been reported frequently in drug-naïve patients living with HIV (Clerinx et al., 1995; Grant et al., 1997; Ole-Nguyaine et al., 2004; Anglaret et al., 2012). Bacterial pneumonia was the most common illness observed in a Ugandan cohort study both before and after ART became available (Iwuji et al., 2011). HIV-1 infection has also been associated with an increased frequency of clinical malaria and parasitaemia and negatively affects the body's immunity mechanism to malaria (Whitworth et al., 2000; Francesconi et al., 2001; Fleteau, Le Loup, & Pialoux, 2011). Increased rates of malarial fever episodes have been documented as CD4 counts decrease (French et al., 2001).

Other serious infections documented in HIV-infected drug-naïve individuals include parasitic infections, cerebral toxoplasmosis, isosporiasis (a protozoal gastrointestinal infection), and fungal infections such as candidiasis, cryptococcosis and cryptococcal meningitis (Lucas et al., 1993; Grant et al., 1997; Anglaret et al., 1999; McCarthy et al., 2006; Iwuji et al., 2011; Anglaret et al., 2012). After controlling for the use of antivirals and antifungals, CD4 counts < 200 cells/ $\mu$ L have been associated with oral candidiasis in women (Greenspan et al., 2000). Viral infections such as oral and genital human papillomavirus have been documented in drug-naïve women living with HIV in a South African study (Richter, Van Rensburg, Van Heerden, & Boy, 2008).

Anaemia in women living with HIV has been shown to be a significant predictor of HIV progression to AIDS and of mortality (Belperio & Rhew, 2004). Anaemia can impact quality of life, causing fatigue and decreased work capacity (Moyle, 2002). In Ghana, ART-naïve patients were five times more likely to develop microcytic hypochromic anaemia compared to patients receiving ART (Owiredu, Quaye, Amidu, & Addai-Mensah, 2011).

The above conditions may cause symptoms that negatively impact the daily lives of HIV-infected individuals. In a study of men and women living with HIV/AIDS in Botswana, Lesotho, South Africa, and Swaziland almost 25% reported spending over 80% of the day in bed (Makoa et al., 2005). While ART status was not reported by the study, 37% of participants received home care to help with their disease (Makoa et al., 2005). Frequently reported symptoms included weakness, fatigue, fear and anxiety, weight loss, painful joints, coughing, lack of

appetite, headaches, muscle aches, night sweats, depression, and dry mouth (Makoe et al., 2005). In South Africa, adults living with HIV and not receiving ART reported painful swallowing, diarrhoea, sore bleeding gums, and sore throat more frequently than those on ART (Peltzer & Phaswana-Mafuya, 2008).

The purpose of this paper is to describe the morbidity experience of HIV-positive, drug-naïve, non-pregnant rural Kenyan women at baseline prior to a nutrition intervention. We report on signs and symptoms experienced on the day of the baseline home visit and during the previous week based on history, physical inspection, CD4 counts, total lymphocyte counts, and cell-mediated immunity response to intradermal testing using tetanus and tuberculosis antigens, and overall nutritional status. The data in this paper were collected at baseline prior to a food-based intervention in rural Kenyan women living with HIV who were not pregnant and had not received ART.

## **Materials and Methods**

**Participants:** Enrolment occurred over a two year period from 2008 to 2010. Women living with HIV who were not pregnant, had not received ART, sought clinical care at the Academic Model Providing Access to Healthcare (AMPATH) centres in Eldoret and Turbo, Kenya or the local government health centre, and had at least one child were invited to participate in a nutrition intervention study. Women were included if their HIV status was classified as WHO Stage 1 or 2 and their CD4 and total lymphocyte counts were above the CD4 count cut-off for ART. Initially, women with CD4 counts  $\geq 250$  cells/ $\mu\text{L}$  were included in the study (as the cut-off for receiving ART in Kenya at that time was a CD4 count  $< 200$  cells/ $\mu\text{L}$ ). However, after the cut-off for receiving ART in Kenya was increased to  $< 350$  cells/ $\mu\text{L}$ , the inclusion criteria were revised to include women with CD4 counts  $\geq 400$  cells/ $\mu\text{L}$ . Women were excluded if they received ART, had experienced one or more opportunistic infections, were pregnant, were allergic to ingredients used in the intervention biscuit, or their family members did not agree to their participation in the study or did not allow community field workers to come to their home because of fear of stigma. The final sample of women whose baseline data is reported in this paper is 226 women.

**Study Area:** Participants lived in the Turbo Division of the Uasin Gishu District of Kenya, a rural area 30 km from Eldoret (altitude ~2 100 metres above sea level) in western Kenya at the rim of the Rift Valley.

**Data collection:** Home visits for morbidity assessment were conducted by three Kenyan nurses who were fully qualified by the government of Kenya to work as nurses and had been working in government health centres in Kenya. They were trained in data collection for this study by several physician study investigators. A structured illness questionnaire was used, and physical inspection and temperature assessment were performed. During the interview a checklist of symptoms and signs including fever, decreased physical activity, being bedridden, or decreased appetite was utilized. Women were asked about the date of their last menstrual period and if there was a possibility that they were pregnant.

Presence of illness was assessed by clinical history and physical examination. Intradermal testing with tuberculin (PPD) was performed to detect tuberculosis—BCG immunization was relatively rare in this adult population. Intradermal testing with candida and tetanus toxoid antigens was also performed to evaluate delayed cutaneous hypersensitivity (cell-mediated immunity). Skin test reactions were read and measured by Kenyan nurses after 48 hours, with indurations  $\geq 5$  mm considered to be positive. Urine samples were collected to test for pregnancy.

If the interviewer, a trained clinical nurse, suspected a serious or life-threatening illness in a study participant, she immediately contacted the clinical officer or project physicians. Symptoms of serious or life-threatening illness included high fever, suspected malaria, productive cough with fever, sudden weight loss, convulsions, severe headache of several days duration, continuous vomiting, or other serious symptoms. A home visit or an immediate visit to the AMPATH clinic or to nearby government clinics was arranged to evaluate such women.

Total lymphocyte, CD3, CD4, and CD8 counts were assessed at baseline using venous blood samples. Cell counts were performed at Moi University, Eldoret using a FACSCALIBER with BD Multitest with Trucount.

Weight, height, sub-scapular fat fold, and triceps skinfold were measured using standardized procedures (Gibson, 2005). Body mass index (BMI) was calculated

(weight/height<sup>2</sup>). Women were weighed and measured with heavy outer garments, belts, amulets, and shoes removed. Women stood barefoot or in lightweight stocking feet on a BWB-800 Digital Professional Scale (Tanita Corporation of America, Inc., Arlington Heights, Illinois, USA). Height was measured using a height measuring board with a sliding head piece. Skin fold thicknesses were measured using a Lange skin fold calliper (Cambridge Scientific Industries, Inc.). Three measurements were taken and then averaged. All measurements were obtained by trained anthropometrists at the project office. Weight, height, and BMI were compared to those of the National Health and Nutrition Examination Survey Non-Hispanic black population of females (Centers for Disease Control and Prevention & National Center for Health Statistics, 2012) as Kenyan reference data is not available.

*Quality control.* Morbidity quality control measures included revisits to a 10% subsample of women on the same day by the clinical officer to confirm morbidity findings and to calculate percent agreement. All data collection forms were reviewed by a physician from AMPATH/Moi University and the clinical officer assigned to the study. Anthropometry data quality control procedures included re-measuring of participants by the anthropometry supervisor on a 10% subsample for percent agreement.

**Ethics:** All study procedures were in accordance with ethical standards and the Declaration of Helsinki and were approved by the government of Kenya, Moi University Institutional Review Board, University of California, Los Angeles (UCLA) Office of the Human Research Protection Program, and the Indiana University Human Research Protection Program. Informed consent was obtained from all research participants. Results have been shared with community stakeholders including physicians and nurses who worked on the study in Kenya. A participant meeting was also held at the end of the fieldwork where data was shared on the morbidities observed and how and where to seek treatment.

**Data coding:** Reported symptoms and observed signs were coded into illness categories in the field and then confirmed at Moi University and UCLA using rules established by physician investigators. These morbidity categories were based upon the symptoms reported by the woman and findings from the nurse's physical inspection. Morbidity categories utilized were similar to categories used in a previous study carried out in rural Kenya (Neumann, Bwibo,

Jiang, & Weiss, 2013). All morbidity episodes were classified as either mild or severe based upon the presence of fever, the type of illness, reported ability to carry out daily activities (i.e. being bedridden), reduced food intake, and need for referral for treatment and further evaluation.

**Statistical analysis:** Descriptive statistics were used to summarize the characteristics of the sample including morbidity episodes, physical inspection, delayed cutaneous hypersensitivity, CD3 counts, CD4 counts, CD8 counts, total lymphocyte counts, haemoglobin, and anthropometric measurements. The associations between baseline morbidity and CD4 counts and morbidity and BMI were analysed using simple *t*-tests. Simple chi-square tests were used to compare morbidity between women who had CD4 counts from 200 to 350 cells/ $\mu$ L and those who had counts > 350 cells/ $\mu$ L. All analyses were conducted using SAS (Cary, North Carolina, USA).

## Results

The average age of study participants was 36 years old (SD 8.01). There were 45 women excluded due to a low CD4 count at baseline, and 21 women were excluded because they were found to be pregnant on baseline pregnancy screening.

**Morbidity.** Seventy-six percent of the women reported being sick on the day of the interview or in the previous week. **Table 1** shows the frequency of morbidities for all participants at baseline. Overall, 13.7% of the women reported morbidity that met the criteria for severe illness (bedridden, febrile, unable to eat, need for additional referral or treatment) on the day of the home visit or during the past week. Most commonly, women reported upper respiratory tract infections (13.3%). Skeletal pain was reported by 4.9% of women. Suspected malaria was reported by 5.9%.

**Physical Inspection.** Few baseline abnormalities were found upon physical inspection on the day that women were interviewed. The complete findings from the physical examination are shown in **Table 2**. On physical inspection three women were febrile, four had ringworm and nine had either pain or swelling of the outer ear. Fourteen percent of women had respiratory signs such as coughing, sore throat, and rhinorrhoea.



**Haematology, Lymphocyte, and Skin Tests.** The mean baseline haemoglobin value was 12.4 g/dL (ranging from 6.8 to 16.3 g/dL) (**Table 3**). **Figure 1** shows the distribution of haemoglobin values at baseline in the study population. Baseline CD3, CD4, CD8, and total lymphocyte counts are given in Table 3. The distribution of CD4 counts in the study population is shown in **Figure 2**. Most women had CD4 counts ranging from 252-1 700 cells/ $\mu$ L. The mean baseline CD4 count was 516.7 cells/ $\mu$ L. Confirmed malaria infection was found in 0.9% of participants via rapid diagnostic malaria testing. Baseline intradermal skin testing showed positive responses to tuberculin (8.4%), candida (7.1%), and tetanus (7.7%)—indicative of delayed cutaneous hypersensitivity (**Table 4**). Immunization histories for participants were not known.

**Anthropometry.** Baseline anthropometric values for weight, BMI, subscapular skinfold, and triceps skinfold are shown in **Table 5**. The mean BMI of the study sample was 22.4 (SD = 3.66). The distribution of BMI in the sample is shown in **Figure 3**.

**BMI and Morbidity.** There were few differences in morbidity by mean BMI (**Table 6**). A positive malaria diagnosis was positively associated with a higher BMI ( $t = 2.67, p = 0.008$ ). Severe diarrhoea was also significantly associated with a higher BMI ( $t = 1.99, p = 0.048$ ).

**CD4 Counts and Morbidity.** No differences in morbidity for any outcome were noted between those who had CD4 counts between 200 - 350 cells/ $\mu$ L and those who had counts >350 cells/ $\mu$ L. For the entire study sample, the only outcomes with significant differences by CD4 count were suspected malaria, ring worm, and skeletal pain. Women with suspected malaria had lower a mean CD4 count ( $M = 410.4$  cells/ $\mu$ L,  $SD = 142.8$ ) compared to women without suspected malaria ( $M = 515.0$  cells/ $\mu$ L,  $SD = 197.4$ ) ( $p = 0.045$ ). Women reporting skeletal pain had higher mean CD4 counts ( $M = 713.1$  cells/ $\mu$ L,  $SD = 405.3$ ) compared to women without skeletal pain ( $M = 500.9$  cells/ $\mu$ L,  $SD = 178.1$ ) ( $p = 0.001$ ). Women with ringworm had higher mean CD4 counts ( $M = 704.9$  cells/ $\mu$ L,  $SD = 348.9$ ) than women without ringworm ( $M = 506.1$  cells/ $\mu$ L,  $SD = 191.4$ ) ( $p = 0.044$ ). We found no other differences in morbidity by CD4 count at baseline in our study sample.

## Discussion

The three most common self-reported and observed morbidities during the baseline health interview and physical inspections were upper respiratory infections, suspected malaria, and skeletal pain. These findings are consistent with morbidities observed in the general population of the study area in previous research conducted in rural Kenya (Neumann, Bwibo, & Sigman, 1992). Women reported symptoms (such as fatigue, skeletal pain, painful joints, cough, and lack of appetite) similar to those reported by adults living with HIV in a study in Botswana, Lesotho, South Africa and Swaziland (Makoae et al., 2005). Our study's participants reported fewer episodes (13.7%) of severe illness (being bedridden) than the multi-country study in which 25% reported spending 80% of the day in bed (Makoae et al., 2005). In adults with HIV/AIDS in Eastern Cape, South Africa, 52% of whom were not receiving ART, the most frequently reported symptoms included headache, fever, weakness, fatigue, painful joints, and nausea (Peltzer & Phaswana-Mafuya, 2008). Women in our study reported many similar symptoms; with the most frequently reported morbidities including upper respiratory infections, suspected malaria, skeletal pain, stomach pain, vaginitis, headache, and toothache. The results of this baseline analyses demonstrate relatively mild, but nonetheless frequent, co-morbidities in this group of women living with HIV who had not received ART. This finding is consistent with our expectations, given that the inclusion criteria for the study stipulated that women could only have Stage 1 or 2 HIV infection.

On average the study women were fairly well nourished with a mean BMI of 22.4—above the 18.5 BMI cut-off point for mild malnutrition (World Food Programme & U.S. Centers for Disease Control and Prevention, 2005). Less than two percent of the women met the BMI criteria for malnourishment (BMI<16) (World Food Programme & U.S. Centers for Disease Control and Prevention, 2005). The minimum BMI observed in study participants was 15. The mean BMI of study participants was similar to the mean BMI observed in women aged 20-49 years in the 2008 Kenya Demographic and Health Survey ( $23.3 \pm 4.36$ ) (Kenya National Bureau of Statistics & ICF Macro, 2010).

Most study participants were not anaemic. The mean haemoglobin value of study participants was 12.4 g/dL (range 6.8 to 16.3), which is slightly above the 12.0 g/dL WHO cut-off point for anaemia in non-pregnant women > 15 years old (World Health Organization, 2011).

WHO recommends that haemoglobin values be adjusted for altitude (World Health Organization, 2006). The altitude of the areas in the study ranged from 1 600 metres (5 250 ft.) in Mautuma to ~1 900 metres (6 350 ft.) above sea level in Soi. If the data were adjusted for an altitude of 1 500 metres above sea level using the WHO's recommendations (World Health Organization, 2006), the mean haemoglobin value would be 11.9 g/dL, which barely falls below the cut-off for mild anaemia. Anaemia and BMI are markers of nutrition status, which impacts immune function. The overall normal nutritional status of the study women likely contributed to their lack of serious comorbidities. Also, participants had near normal CD4 count values, indicating that their immune function was not yet greatly compromised. They showed lower mean CD3 and CD4 counts but higher mean CD8 counts than those observed in healthy adult Kenyan women described in a recent study (Bosire et al., 2013). Total lymphocyte counts also appeared to be in the normal range. Given these indicators of nutritional and immune status, few opportunistic infections were identified at baseline.

Another factor that may have contributed to the relatively low prevalence of severe illness in the study women was their ready access to primary health care at the AMPATH clinics and government primary health care centres. The AMPATH clinics partner with multiple international organizations and universities to provide not only HIV care, but care for many common health conditions.

While this paper is limited in that it describes the morbidity experience of a relatively small number of drug-naïve women living with HIV in rural western Kenya, it provides data that can inform discussions regarding the health of women living with HIV early in the course of their infection. The nutritional and overall health status of the study women was not severely compromised, and they appeared to be in reasonably good health. These women, although not receiving ART, had available quality primary and specialty care. However, with 76% of the women reporting being sick on the day of the interview or in the previous week, their reported morbidity episodes were frequent.

An unexpected finding in the study group was that diagnosed malaria and severe diarrhoea were associated with a higher BMI. The association with diagnosed malaria may be due to women with a higher BMI being more likely to be bitten by mosquitos. While study

participants were not pregnant, studies of pregnant women have shown them more likely to be bitten by mosquitos perhaps due to higher body temperatures and increases in expired carbon dioxide, which attracts mosquitos (Lindsay et al., 2000; Himeidan, Elbashir, & Adam, 2004). HIV lipotrophy has also been associated with an increase in mosquito bites due to a more accessible capillary network near the skin's surface (Greub, Fellay, & Telenti, 2002). Higher BMI may be associated with higher temperature of exhaled breaths (Bijnens et al., 2013) as well as an increased body surface area for mosquitos to feed on. Cell-mediated immunity has also been noted to be diminished in obesity (Chandra, 1980; Sheridan et al., 2012). While the mechanism for this observation cannot be completely explained, the observation of an association between higher BMI and diagnosed malaria points to possible areas for future research.

This paper discusses women in the early stages of HIV infection and still fairly free of serious illness. These women were not eligible for ART under the treatment guidelines that were in place at the time the study was conducted. However, under current treatment guidelines all of the women in the study would have been eligible for ART treatment. We do not have data regarding how long these women had been HIV-positive. Long-term studies would likely show deterioration of their health status without introduction of ART. Treatment for individuals who are HIV-positive should not be delayed. Over time their nutritional status will likely deteriorate, especially in locations where the food supply may vary and is not always reliable. They are also at risk for serious infections, especially TB and malaria, which could further adversely impact their immune status. The recent changes to international treatment guidelines will help prevent deterioration of these women who previously may not have had access to ART at the time when their CD4 counts dropped following a serious infection or nutritional insult. Treating all women living with HIV will improve women's viral suppression, health outcomes, and overall quality of life. This will contribute to the achievement of the 90-90-90 treatment target set by the United Nations (Joint United Nations Programme on HIV/AIDS, 2014).

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**Table 1. Frequency in descending order of morbidities for all study participants at baseline (N=226)**

<b>Type of Illness</b>	<b>%</b>
Sick today or a week ago	76.7
Severe Illness	13.7
URI	13.3
Malaria Suspected	5.85
Skeletal Pain	4.87
Stomach Pain	4.42
Vaginitis	3.98
Headache	3.54
Tooth Ache	3.54
Viral Syndrome	3.10
No Specific Diagnosis	2.78
Febrile Unspecified	2.65
Eye Infection	1.77
Diminished Night Vision	1.77
Ring Worm	1.77
Skin Conditions	1.77
Ear Pain	1.33
URI (w/ Ear Infection)	1.33
Asthma	0.88
Heartburn / Ulcer	0.88
Malaria Diagnosed	0.88
Trauma	0.88
Urinary Infection	0.88
Bronchitis Fever	0.44
Convulsion	0.44
Genitourinary Other	0.44
Oral Thrush	0.44
Pneumonia	0.44
Severe Diarrhea	0.44

Abbreviations: URI: Upper Respiratory Infection

<b>Table 2. Frequency of baseline abnormal physical signs on inspection (N=226)</b>		
<b>Type of Illness</b>	<b>N</b>	<b>%</b>
<b>General Appearance</b>	<b>10</b>	<b>4.42</b>
Fever	3	1.32
Acutely Ill	3	1.32
Restless	4	1.76
<b>Skin</b>	<b>12</b>	<b>5.61</b>
Ringworm	4	1.86
Rash	7	3.27
Other	1	0.44
<b>Face</b>	<b>2</b>	<b>0.88</b>
Swollen Cheeks	2	0.88
<b>Neck</b>	<b>2</b>	<b>0.88</b>
Swollen Glands	2	0.88
<b>Eyes</b>	<b>4</b>	<b>1.76</b>
Redness	3	1.32
Strabismus	1	0.44
<b>Ears</b>	<b>9</b>	<b>3.98</b>
Painful Outer Ear	8	3.54
Swelling of Outer Ear	1	0.44
<b>Nose</b>	<b>6</b>	<b>2.65</b>
Watery Discharge	6	2.65
<b>Mouth/Throat</b>	<b>5</b>	<b>2.21</b>
Red Throat or Tonsils	3	1.32
Blisters	2	0.88
<b>Respiratory System</b>	<b>31</b>	<b>13.7</b>
Common Cold	9	3.98
Rapid Breathing	2	0.88
Coughing	20	8.85
<b>Nervous System</b>	<b>2</b>	<b>0.88</b>
<b>Abdomen</b>	<b>4</b>	<b>1.76</b>
Pain or Masses on Palpation	4	1.76

**Table 3. Hemoglobin, CD3, CD4,CD8,and Total Lymphocyte Counts at Baseline  
(N=226)**

	<b>Mean</b>	<b>SD</b>	<b>Min</b>	<b>Max</b>
Hemoglobin (grams/dL)	12.4	1.7	6.8	16.3
CD3 count (cells/ $\mu$ L)	1462.1	523.0	547.7	3576.4
CD4 count (cells/ $\mu$ L)	516.7	224.0	252.2	1706.0
CD8 count (cells/ $\mu$ L)	920.7	457.8	76.0	2997.2
Total Lymphocytes (cells/mm <sup>3</sup> )	1864.4	639.3	755.2	4889.8

**Table 4. Baseline Test Results for Drug Naïve Mothers (N=226)**

	<b>N</b>	<b>Positive N</b>	<b>Positive %</b>
Malaria (rapid test on blood)	226	2	0.9
Tuberculin (DCH*)	226	19	8.4
Candida (DCH*)	226	16	7.1
Tetanus (DCH*)	226	18	7.7

\*DCH: Delayed cutaneous hypersensitivity with induration  $\geq 5$ mm considered as positive result



**Table 5. Anthropometry at baseline (N=226)**

	<b>Mean</b>	<b>SD</b>	<b>Min</b>	<b>Max</b>
Weight (kg)	58.6	10.5	37.2	84.2
BMI (weight in kg/m <sup>2</sup> )	22.39	3.66	15.04	32.35
SSF (mm)	13.0	6.92	4.00	43.6
TSF (mm)	16.9	7.3	2.0	49.0

Abbreviations: BMI: body mass index; SSF: subscapular skin fold; TSF: triceps skinfold

**Table 6. Mean BMI by morbidity at baseline (N=226)**

<b>Type of Illness</b>	<b>N</b>	<b>Mean (SD)</b>	<b>T-Test</b>	<b>P - Value</b>
Severe Illness				
Yes	18	23.12 (3.72)	0.60	0.548
No	194	22.49 (4.83)		
Asthma				
Yes	2	21.63 (3.13)	-0.30	0.766
No	224	22.41 (3.61)		
Bronchitis with a Fever				
Yes	1	23.69	0.35	0.728
No	225	22.40 (3.61)		
Convulsion				
Yes	1	21.76	-0.18	0.860
No	225	22.41 (21.97)		
Ear Pain				
Yes	3	20.34 (2.12)	-0.98	0.328
No	223	22.44 (3.62)		
Eye Infection				
Yes	4	21.47 (0.95)	-0.51	0.609
No	222	22.42 (3.64)		
Febrile Unspecified				
Yes	5	22.85 (4.88)	0.27	0.784
No	221	22.40 (3.66)		
GU Other				
Yes	1	17.55	-1.32	0.187
No	225	22.43 (3.68)		
Headache				
Yes	7	22.28 (2.72)	-0.09	0.929
No	219	22.41 (3.64)		
Heartburn Ulcer				
Yes	1	19.42	-0.81	0.417
No	225	22.42 (3.69)		
Malaria Diagnosed				
Yes	2	29.23 (4.14)	2.67	0.008
No	224	22.34 (3.55)		
Malaria Suspected				
Yes	12	22.46 (4.47)	0.05	0.957
No	214	22.40 (3.64)		
Night Vision				
Yes	4	21.43 (3.51)	-0.53	0.594
No	222	22.43 (3.61)		
Oral Thrush				
Yes	1	20.35	-0.58	0.560
No	225	22.42 (3.68)		

Pneumonia				
Yes	1	20.45	-0.55	0.571
No	225	22.47 (3.61)		
Ring Worm				
Yes	4	25.21 (2.54)	1.54	0.124
No	222	22.40 (3.61)		
Severe Diarrhea				
Yes	1	29.67	1.99	0.048
No	225	22.37 (3.58)		
Skeletal Pain				
Yes	11	23.11 (3.95)	0.65	0.517
No	215	22.37 (3.67)		
Skin				
Yes	4	22.30 (5.40)	-0.06	0.956
No	222	22.41 (3.66)		
Stomach Pain				
Yes	8	23.87 (4.14)	1.15	0.252
No	218	22.35 (3.58)		
Tooth Ache				
Yes	8	20.68 (3.58)	-1.36	0.177
No	218	22.47 (3.69)		
Trauma				
Yes	2	20.46 (0.88)	-0.75	0.455
No	224	22.42 (3.69)		
URI with Ear Infection				
Yes	3	19.18 (1.60)	-1.53	0.127
No	223	22.45 (3.68)		
URI No Ear Infection				
Yes	30	22.98 (4.03)	0.92	0.413
No	196	22.32 (3.63)		
UTI				
Yes	4	21.59 (1.58)	-0.45	0.183
No	222	22.42 (3.71)		
Vaginitis				
Yes	9	20.99 (3.16)	-1.18	0.669
No	217	22.47 (3.62)		
Viral Syndrome				
Yes	6	21.67 (4.25)	-0.49	0.623
No	220	22.43 (3.67)		
Other				
Yes	3	22.70 (6.03)	0.14	0.891
No	223	22.40 (3.66)		

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