An Assessment of Health Outcomes Among Orphans in the Positive Outcomes for Orphans Study in Rural Settings of Kenya and Tanzania

by

Dunstan Eugine Achwoka

Duke Global Health Institute
Duke University

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Nathan Thielman, Supervisor

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Wendy O'Meara

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Mabel Nangami

Thesis submitted in partial fulfillment of the requirements for the degree of Master of Science in the Duke Global Health Institute in the Graduate School of Duke University

2011
ABSTRACT

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Abstract

Objectives: To compare measures of health and health quality between Orphans and Vulnerable Children (OVC) in different living arrangements--institutional and community care; and to correlate different measures of OVC health and health quality using clinical, laboratory and quality of life instruments.

Design: Cross-sectional study.

Setting: Two rural districts (sites) in East Africa, Bungoma in Kenya, and Kilimanjaro in Tanzania.

Participants: 77 male and 45 female OVC aged 16-18 years (N=122).
Participants, who had attained a minimum age of 16 at the date of interview, were selected from the larger sample of OVC in the Positive Outcomes for Orphans (POFO) study. POFO, a longitudinal study in five less wealthy countries that started in 2006, obtained its sample through cluster randomization.

Methods: To obtain self-ratings of OVC physical health, OVC responded to an interviewer administered SF-36 questionnaire, a multipurpose generic measure of health status. A neutral examiner then measured OVC physical health using 4 clinical variables: a physical health examination, body mass index, hemoglobin level, and the Harvard physical fitness score.

Main Outcome Measures: SF-36 scores presented as a two component score-the physical health and mental health composite sub-scores. For physical health,
normal findings for age were considered as meeting the threshold for good physical health.

**Results:** Of the 122 OVC, 89 (73%) lived in the community while 33 (27%) lived in institutional settings. For the SF-36, the mean physical composite score for the entire study population was 50.6 (SD=6.2). Mean body mass index (BMI) was 19.3 (SD=2.4). Mean hemoglobin was found to be 13.2g/dl (SD=1.8). The average Harvard physical fitness score was found to be 40.7(SD=16.9).

Pearson’s correlations between SF-36 Physical Functioning and hemoglobin, BMI, and the Harvard Step-Test fitness score were 0.1, 0.1, and -0.1 respectively. There was no evidence that self-rating of OVC health outcomes differed by living arrangement. Using paired *t*-tests for continuous variables and chi-square tests for categorical variables, no significant *p*- values were obtained at the 95% level. Using a threshold of vision 20/20 for normal vision, 91.0% of community OVC and 78.8% of OVC in institutions had normal vision (p=0.07).

**Conclusion:** Although this study did not detect significant differences in self-reported measures of health among OVC in different living arrangements, physical examination revealed a slightly high incidence of poor vision among those living in institutions. In this sample, the correlations between SF-36 physical functioning sub-score and 3 physical health outcomes of BMI, hemoglobin, and the Harvard Step-test fitness score were weak.
Dedication

To my dear family: My wife Ruth, my daughter Neema, and my son Leon.

*You are the strongest pillar in my life.*
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I wish to also thank my research committee for their helpful suggestions, advice, multiple reviews of my draft manuscripts and detailed comments: Nathan Thielman, both my supervisor and mentor; Wendy O’Meara; and Mabel Nangami.

I have benefitted immensely from the work of Positive Outcomes for Orphans (POFO) study researchers, field personnel and partner organizations—ACE-Africa and the Tanzania Women Research Foundation, (TAWREF). All of
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Finally, and not the least, I am thankful for all my friends and family who stood with me throughout the course of my studies. I appreciate all your prayers and good wishes. Without your constant support, I certainly would not have made it this far. Thank you.
1. Introduction

The population of Orphans and Vulnerable Children (OVC) has been on the rise in recent years [1]. Thirty years on, the HIV/AIDS pandemic continues to fuel the OVC crisis, and in Sub-Saharan Africa, it remains the leading cause of new orphans [1, 2]. With most of these children living in resource poor settings, policy makers have increasingly become concerned on OVC future outcomes. In particular, OVC health outcomes are now taking a center stage presence.

Several studies on OVC, albeit in retrospect, continue to report mixed health outcomes [3-7]. To determine the physical health of orphans under their custody, most of these studies use proxy-reports of caregivers [7, 8]. In some of these studies, the Cinderella hypothesis, the notion that caregivers may prioritize their own children over the fostered child, has been sustained [5]. A few studies have also assessed OVC physical health using OVC self-reports [9]. In the Positive Outcomes for Orphans Study (POFO), among caregivers and pre-adolescents OVC, Whetten and colleagues (2010), demonstrate a strong direct correlation for poor health between caregiver reports of health and OVC reports of health. Caregivers who reported poor health were more likely to report poor health in OVC under their custody [10]. Thus, most studies among pre-adolescents that utilize both self and proxy reports reveal a positive correlation.

In contrast, studies on quality of life and health outcomes in older school-going children and adolescents that utilize both proxy and self-reports, at best, obtain fair to moderate concordance [11]. Considering, the numerous challenges
that adolescent OVC face, such as an increased risk of early sexual debut as compared to their non-orphans counterparts, this low concordance bears important implications for policy and healthcare and highlights the need to explore measures of adolescent orphan health more fully [2, 12].

Assessing health outcomes for teenage OVC represents an opportunity for informing policy and planning. Yet in the literature of teenage OVC health outcomes, a dearth exists. Currently, most research on adolescents OVC health either utilizes generic measures to assess general health or assesses specific health conditions. To date, studies that attempt to obtain health outcomes among teenage orphans through a holistic approach incorporating the child, the caregiver and a neutral professional examiner are lacking.

Through this study, I seek to address this gap in the literature by combining both generic health measurement using the Short Form 36 (SF-36) tool and a comprehensive health assessment. The latter includes a physical health examination, anthropometric measurement of body mass index, determination of hemoglobin level, and the Harvard Step physical fitness test. For this paper, I examined the following two questions:

a. Are there differences in health measures between teenage OVC living in the community when compared to those living in institutions?

b. How does OVC health correlate with different measures of health and health quality using clinical, laboratory and quality of life instruments?
2. Methods and Materials

2.1 Field-site Description

A cross-sectional survey was conducted among orphans enrolled in rural sites of the Positive Outcomes for Orphans Study (POFO), in 2 East-African countries – Kenya and Tanzania. Other than the two countries, the POFO study has enrolled participants from 3 more countries: Ethiopia, Cambodia, and India. This multi-country study is longitudinal in nature and seeks positive outcomes for orphans in multiple dimensions, among which is health. In Kenya, the interviews and health examinations were conducted from May 2010 to July 2010 in Bungoma District of Western province. In Tanzania, interviews and health examinations were conducted in Moshi on the Kilimanjaro region in September 2010. Descriptions of the two rural sites in both Kenya and Tanzania, are found elsewhere [13].

2.2 Sampling

POFO participants enrolled into this study, had been previously selected through a two-stage randomization at the country level, and cluster randomization at the institution and community levels [14]. Additionally, participants of either gender, had to meet the following criteria: 1) be registered in the POFO database, 2) be 16 years of age or more, at the time of the interview and health examination, and, 3) be either living in an institution or the community. Participants found to be pregnant, with physical disabilities or
illnesses that constrained their performance of physical exercise, were excluded from the Harvard Step fitness test.

At the commencement of the data collection, a query was made on the POFO database. In Bungoma, there were 98 eligible orphans for the study, while in Moshi there were 151 eligible orphans. Two interviewers and the researcher contacted 61 orphans (62.2%) in Bungoma. We were unable to make contact with 37 orphans for the following reasons: 1) 13.2% of the orphans who study in boarding schools and distant locations (outside the region), were unavailable until official school break; 2) 20.5% were lost to follow-up; and 3) 4.1% were not reached despite three visits to their last known location. Similarly, in Moshi 61 orphans (40.4%) were contacted. We were unable to make contact with 94 orphans for the following reasons: 1) 20.5% of the orphans study in boarding schools and were inaccessible until official school break; 2) 6.6% declined to participate in the study; and 3) 32.5% had migrated to other towns in Tanzania. The total sample size in both Kenya and Tanzania was 122 orphans.

Research protocols for this study were approved alongside those of Round 8 of the POFO study by ethical review committees at Duke University, Kenya Medical Research Institute (KEMRI), and the Kilimanjaro Christian Medical Center (KCMC).

The survey instrument consisted of old questions from POFO I (POFO rounds 1-7) plus new questions added in round 8 that were intended to address the specific aims of POFO II grant. POFO interviewers, who are native Swahili
speakers, translated the SF-36 questionnaire from English to Swahili. Different translators were used for the translations and back-translations to English. The original English text and English back-translation were then reviewed by Duke Staff to ensure that the content was correct. In both study sites, local adult and youth community advisory boards (CABS) reviewed the new questions for round 8 of POFO and made comments regarding the acceptability and appropriateness of the language. They also helped identify response options for some questions.

Two interviewers in each study site administered the questionnaire to the participants. The researcher was blinded to both the SF-36 questionnaire and the participants’ SF-36 survey responses. After the interview, the interviewers alerted the researcher who subsequently conducted the OVC health assessment.

2.3 Measures

2.3.1 General Health

General health was measured in the questionnaire using the Short Form-36 scale (SF-36) health survey adopted from the Medical Outcomes Trust, Boston, MA [15]. Although the SF-36 has been documented in more than 4000 publications [16], and been translated into over 60 languages including a Swahili version for use in Tanzania [17] for this study, the SF-36 was translated from English to Swahili by trained POFO field interviewers. The SF-36 is a multipurpose generic measure of health status that is non-specific to age, disease, or treatment group and consists of 36 items. It yields an 8-scale profile of scores and 2 summary measures. The 8 scores are: physical functioning,
physical role, bodily pain, general health, vitality, social functioning, emotional role, and mental health. Scores are transformed to a 0-100 scale, with higher scores reflecting better health [11]. The two health summary measures are the physical health component score, and the mental health component score [18].

2.3.2 Health Assessment

The health assessment measured participants' physical health using 4 clinical variables. These included the following: 1) complete physical health examination; 2) anthropometric measurement of body mass index (BMI); 3) hemoglobin level; and, 4) physical fitness testing by means of the Harvard Step Test. In situations where pathological conditions were detected, the researcher counseled the participant before making a referral to the local district hospital. In all cases, test results were explained to the study participants. 34 referrals were made; 6 from the institutions, and 28 from the community.

Anthropometric measurements of weight and height of the orphans were performed to obtain the BMI, which is the weight in kilograms divided by the height in meters squared $(\text{kg/m}^2)$. Weight was measured to the nearest 0.1kg on a calibrated digital bathroom scale. Standing height was measured from a flat surface and expressed to the nearest 0.1cm using a wooden foldable measurement ruler.

Quantitative determination of hemoglobin and a calculated value for hematocrit were obtained through 10µL specimen of capillary blood collected through a sterile finger prick. The blood was placed onto a Hemoglobin Test Strip
and affixed onto a portable Mission ® Hemoglobin Meter manufactured from ACON Laboratories, Inc. San Diego, CA 92121 USA. The strips function by lysing erythrocytes and converting the released hemoglobin into methemoglobin.

Cardiorespiratory fitness was assessed through the Harvard Step Test [19]. The test is considered submaximal since the subject works below maximum effort. Extrapolation is used to estimate maximum capacity. The test was originally conducted among young men aged 17-27 years, and has been adapted and validated among different teenage populations in the US, India and East-Africa [19-21]. It involves stepping onto and down from a platform 20 inches high, 30 times a minute for 5 minutes, or until the subject is unable to continue. Once the exercise is completed, the participant’s pulse is counted during the periods, 1-1.5, 2-2.5, and 3-3.5 minutes. A fitness index is then calculated as: $\text{Fitness Index} = \frac{(100 \times \text{Exercise duration (sec)})}{(2 \times \text{sum of the 3 pulse counts})}$. It is then interpreted as: excellent > 90; good 80 – 89; high average 65 – 79; low average 55- 64; and, poor < 55.

### 2.4 Change in Methodology

Although the study had IRB approval to assess for HSV-2 antibodies, the absence of a consensus on a HSV-2 test-result disclosure protocol to OVC caregivers led the larger team of POFO investigators to unanimously stop the test mid-study. At this point, 63 (52%) of the OVC had been tested for HSV-2 antibodies and they all tested negative for HSV-2 antibodies.
2.5 Analysis

Data were analyzed using STATA/IC version 11.2. Univariate and bivariate analyses comparing health outcomes between teenage OVC living in the community and those living in institutions were conducted using Chi-square tests for categorical variables and t-tests for continuous variables. Multivariate analyses were conducted to compare SF-36 physical functioning scores and objective physical health outcomes of hemoglobin, BMI, and Harvard Step-Test fitness scores. Pearson’s correlations were then sought.
3. Results

3.1 Demographic Characteristics

Study participants in Bungoma, Kenya and Kilimanjaro region in Tanzania were drawn from the POFO study sample - a longitudinal multi-site study. The total enrollment was 122 participants, with 50% of the study sample being derived from either country. A majority of the participants were male (63.1%). On average, participants were 16.8 years old (SD = 0.5). The main living arrangement was in the community (73.0%), with over a quarter (27.0%) living in institutions (see table 1).

The 139 eligible OVC that were not contacted had an average age of 16.9 years (SD=0.5), with 48% living in the community and 52% in institutions.

Table 1. Sociodemographic Characteristics of Study Participants

<table>
<thead>
<tr>
<th></th>
<th>(n=122)</th>
<th>Kenya (n=61)</th>
<th>Tanzania (n=61)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (M, SD)</td>
<td>16.8(0.5)</td>
<td>16.6(0.6)</td>
<td>17.0(0.8)</td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female (%)</td>
<td>36.9</td>
<td>32.8</td>
<td>41.0</td>
</tr>
<tr>
<td>Male (%)</td>
<td>63.1</td>
<td>67.2</td>
<td>59.0</td>
</tr>
<tr>
<td>Living Arrangement</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Community (%)</td>
<td>73.0</td>
<td>65.6</td>
<td>80.3</td>
</tr>
<tr>
<td>Institution (%)</td>
<td>27.0</td>
<td>34.4</td>
<td>19.7</td>
</tr>
</tbody>
</table>
3.2 Health Characteristics

OVC living in community settings and those living in institutions were found to have similar health outcomes. When compared by a neutral examiner along 4 different health indicators, (physical examination, body mass index, hemoglobin levels, and the Harvard test score of physical fitness), no significant differences were found. Although 97.5% of the OVC in both community and institutional settings were found to be in good physical health, the mean Harvard test score of physical fitness for all OVC was classified as poor \( \bar{x} = 40.7; \) SD=16.9. Of the 11 OVC found to have a resting tachycardia (heart rate of above 100 beats per minute), 9 were females (82.0%). Incidence of poor vision was 12.3%, though none wore glasses. Among the 77 male OVC in the entire sample, 73 were circumcised (98.4%) (see table 2).
Table 2. Differences in Health Outcomes Among OVC in Community and Institutional Settings

<table>
<thead>
<tr>
<th>Physical Examination</th>
<th>Community (n=89)</th>
<th>Institution (n=33)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Good General Appearance (n, %)</td>
<td>119(97.5)</td>
<td>33(100)</td>
<td>0.3</td>
</tr>
<tr>
<td>• Normal Visual Acuity 20/20 (n, %)</td>
<td>107(87.7)</td>
<td>26(78.8)</td>
<td>&lt;0.1†</td>
</tr>
<tr>
<td>• Normal Hearing (n, %)</td>
<td>119(97.5)</td>
<td>33(100)</td>
<td>0.3</td>
</tr>
<tr>
<td>• Normal Head Findings (n, %)</td>
<td>122(100)</td>
<td>33(100)</td>
<td>-</td>
</tr>
<tr>
<td>• Normal EENT Findings (n, %)</td>
<td>113(92.6)</td>
<td>30(90.9)</td>
<td>0.7</td>
</tr>
<tr>
<td>• Normal Chest Findings (n, %)</td>
<td>120(98.4)</td>
<td>33(100)</td>
<td>0.4</td>
</tr>
<tr>
<td>• Normal Abdominal Findings (n, %)</td>
<td>120(98.4)</td>
<td>33(100)</td>
<td>0.4</td>
</tr>
<tr>
<td>• Systolic Blood Pressure (mmHg) (M, SD)</td>
<td>115(9.7)</td>
<td>113(12.4)</td>
<td>0.4</td>
</tr>
<tr>
<td>• Diastolic Blood Pressure (mmHg) (M, SD)</td>
<td>66(8.4)</td>
<td>66(9.8)</td>
<td>0.9</td>
</tr>
<tr>
<td>• Resting Pulse (b/pm) (M, SD)</td>
<td>75(15.7)</td>
<td>71(15.4)</td>
<td>&lt;0.1†</td>
</tr>
<tr>
<td>• Male (M,SD)</td>
<td>70.4(13.8)</td>
<td>65.7(12.4)</td>
<td></td>
</tr>
<tr>
<td>• Female (M,SD)</td>
<td>83.7(15.3)</td>
<td>81.3(16.0)</td>
<td></td>
</tr>
<tr>
<td>BMI (kg/m²) (M, SD)</td>
<td>19.4(2.4)</td>
<td>19.4(2.2)</td>
<td>0.9</td>
</tr>
<tr>
<td>• Male (M,SD)</td>
<td>18.9(2.0)</td>
<td>18.9(1.5)</td>
<td></td>
</tr>
<tr>
<td>• Female (M,SD)</td>
<td>20.3(2.8)</td>
<td>20.5(3.0)</td>
<td></td>
</tr>
<tr>
<td>Hemoglobin (g/dl) (M, SD)</td>
<td>13.2(1.8)</td>
<td>12.8(1.6)</td>
<td>0.2</td>
</tr>
<tr>
<td>• Male (M,SD)</td>
<td>13.5(1.7)</td>
<td>13.1(1.6)</td>
<td></td>
</tr>
<tr>
<td>• Female (M,SD)</td>
<td>12.5(1.7)</td>
<td>12.2(1.4)</td>
<td></td>
</tr>
<tr>
<td>Harvard Test Score (M, SD)</td>
<td>40.7(16.9)</td>
<td>38.5(8.3)</td>
<td>0.4</td>
</tr>
<tr>
<td>• Male (M,SD)</td>
<td>44.7(16.0)</td>
<td>45.2(15.1)</td>
<td></td>
</tr>
<tr>
<td>• Female (M,SD)</td>
<td>32.5(16.0)</td>
<td>24.9(17.1)</td>
<td></td>
</tr>
<tr>
<td>Standardized SF-36 Physical Composite Score (M, SD)*</td>
<td>50.6(6.2)</td>
<td>49.6(6.7)</td>
<td>0.3</td>
</tr>
<tr>
<td>• Male (M,SD)</td>
<td>50.7(6.1)</td>
<td>50.6(6.5)</td>
<td></td>
</tr>
<tr>
<td>• Female (M,SD)</td>
<td>50.3(6.4)</td>
<td>47.6(6.9)</td>
<td></td>
</tr>
<tr>
<td>Standardized SF-36 Mental Composite Score (M, SD)*</td>
<td>48.2(9.1)</td>
<td>47.0(8.9)</td>
<td>0.4</td>
</tr>
<tr>
<td>• Male (M,SD)</td>
<td>47.5(9.4)</td>
<td>47.2(9.0)</td>
<td></td>
</tr>
<tr>
<td>• Female (M,SD)</td>
<td>49.3(8.6)</td>
<td>46.5(9.0)</td>
<td></td>
</tr>
</tbody>
</table>

† p<0.1; *SF-36 scores are standardized to US general population norms[15, 18]
In this sample, the SF-36 showed a high level of internal reliability (Cronbach’s $\alpha = 0.86$). Participants reported a mean standardized physical composite score of 50.6 (SD=6.2) and a mean standardized mental composite score of 48.2 (SD=9.1). Between the OVC groups, there was no note of a statistically significant difference.

![Figure 1. SF-36 Scores of Study Participants (n=122)](image_url)

**Figure 1. SF-36 Scores of Study Participants (n=122)**

PF is physical functioning; RP is physical role; BP is bodily pain; GH is general health; VT is vitality; SF is social functioning; RE is emotional role; MH is mental health; PCS is physical composite score; and MCS is mental composite score.
Table 3. Mean Item Scores for items of the SF-36 Physical Functioning scale in Study Participants and other Studies from Tanzania and the US

<table>
<thead>
<tr>
<th>Item content</th>
<th>Mean item score</th>
<th>OVC (n=122)</th>
<th>Tanzania† (n=3,802)</th>
<th>US‡ (n=2,474)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vigorous Activities</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Climbing Several flights</td>
<td>2.71</td>
<td>2.74</td>
<td>2.17</td>
<td></td>
</tr>
<tr>
<td>Bending, kneeling, stooping</td>
<td>2.78</td>
<td>2.89</td>
<td>2.59</td>
<td></td>
</tr>
<tr>
<td>Walking more than a km</td>
<td>2.80</td>
<td>2.90</td>
<td>2.55</td>
<td></td>
</tr>
<tr>
<td>Moderate Activities</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lifting or carrying groceries</td>
<td>2.76</td>
<td>2.88</td>
<td>2.72</td>
<td></td>
</tr>
<tr>
<td>Walking several hundred meters</td>
<td>2.72</td>
<td>2.94</td>
<td>2.69</td>
<td></td>
</tr>
<tr>
<td>Climbing one flight</td>
<td>2.75</td>
<td>2.88</td>
<td>2.78</td>
<td></td>
</tr>
<tr>
<td>Walking 100 meters</td>
<td>2.74</td>
<td>2.95</td>
<td>2.82</td>
<td></td>
</tr>
<tr>
<td>Bathing or dressing</td>
<td>2.89</td>
<td>2.98</td>
<td>2.88</td>
<td></td>
</tr>
</tbody>
</table>

† Source: Wagner and colleagues [17]. The Tanzanian sample was a population sample aged 15 years and above.
‡ US data is from a general population sample of adults who completed the SF-36 within a survey conducted for the Health Institute by the National Opinion Research Center [17].

3.3 Multivariate Analysis

Stratifying along gender, Pearson’s correlations between SF-36 physical functioning (SF-36 PF) sub-score and 3 health outcomes were weak. It was 0.1 between SF-36 PF and hemoglobin, 0.1 between SF-36 PF and BMI, and -0.1 between SF-36PF and the Harvard Fitness score. Similarly, correlations with the Harvard Fitness score were weak. It was -0.4 between the Harvard Fitness score and BMI, -0.5 between the Harvard Fitness score and resting pulse, and 0.2 between the Harvard Fitness score and height.
Figure 2. Comparison of Study Participants’ (n=122), SF-36 Physical Sub-scores with Hemoglobin Levels by Gender

Figure 3. Comparison of Study Participants’ (n=122), SF-36 Physical Functioning Sub-scores with BMI by Gender
Figure 4. Comparison of Study Participants’ \( n=122 \), SF-36 Physical Functioning sub-scores with Harvard Step-Test Fitness scores by Gender

Figure 5. Comparison of Study Participants’ \( n=122 \), Harvard Step-Test Fitness Score with BMI by Gender
4. Discussion and Conclusion

In this study, when physical health outcomes and self-rated quality of health measures were compared among OVC living in institutions versus those living in the community, no difference was found. Applying US general population norms to the SF-36 generic health questionnaire, regardless of living arrangement, all OVC had an above-average composite score for physical health. For a majority of the OVC, physical examination revealed normal findings for blood pressure, head, EENT, chest, abdominal, and extremities. However, of note was a high prevalence of undiagnosed poor visual acuity. Most rural areas, from which the sample was drawn from, lacked access to eye-care centers. The insidious, non-painful nature of most eye illnesses, and poor access to Vitamin-A rich dietary sources, also serve to increase the prevalence of poor visual acuity.

When adjusted for age and gender, BMI and hemoglobin levels were found to be within normal reference standards [22, 23]. Incidences of both underweight and anemia conditions in both community and institutional settings were low and homogenously spread. Despite age-appropriate physiological indices, the average fitness score obtained from the Harvard Step test was poor. This observation could be attributed to several factors. Participants of a short stature, females who wore tight or short clothing inappropriate for physical exercise, absence of privacy when the test was conducted, and anxiety among participants may have had a major negative impact on test performance.

Correlates between SF-36 physical functioning sub-scores and 3 physical health outcomes of hemoglobin, BMI, and the Harvard Step-Test fitness score,
were weak. The 3 health outcomes were chosen as they provided the most objective continuous variables for comparison purposes. Nonetheless, plotted against the SF-36 composite score for physical health, all the 3 outcomes showed little association.

Although this is among the first few studies to examine OVC health ratings at ages above 16, findings of no difference by living arrangements have been reported before. Drawing from ages 6-12 of the larger POFO sample, Whetten and colleagues found the health of OVC to be no worse in institutions than in the community[10]. Consistent with this finding are results from Uganda, Ethiopia, and rural China [9, 24, 25]. In Uganda, despite findings of higher prevalence of self-reported morbidity in orphans than non-orphans, Sarker and colleagues found no differences in reported health seeking behavior and measured anthropometric parameters [24]. However, despite the findings in support for no difference in health outcome in group homes and institutional care, for chronically ill orphans, such as with HIV/AIDs, social and cultural contexts of the living arrangements matter [25]. Thus, this study reaffirms the finding of no difference in health outcomes for OVC living in different arrangements.

On the second finding in this study of a weak correlation between SF-36 and the 3 chosen physical outcomes, literature is mixed. Overall, the SF-36 composite scores obtained in this study are above average [15] .Consistent with this finding, is a study from Mozambique [26]. While examining anthropometric measures among school-going children and adolescents, using the recommended cut-offs were, Prista and colleagues were unable to establish the
biological meaning of BMI. Other studies are more cautious. Despite finding an association of a higher BMI with a worse performance in some physical fitness tests, Monyeki and colleagues, preferred to interpret BMI as an indicator of muscle mass [27]. However, working in rural Senegal, Benefice and colleagues find that activity levels are less dependent on physiological characteristics in children in traditional subsistence societies. For instance, they found that adult women had better cardiorespiratory fitness and were more active than adolescent girls [28].

Inherent in this study are several limitations. The first relates to the characteristics of the study sample. Not only was the study sample inadequately powered, but also non-random refusal to participate led to skewed gender, age and living arrangements distributions. Hence, the generalizability of the results presented in this paper is limited. Secondly, the results are generalizable only to OVC aged above 16 years in rural East-African settings. The narrow age range of the sample, may further explain the lack of variability in the results. Thirdly, the absence of local references for BMI and an appropriate comparison group for the SF-36, limit the comparability of these results. Finally, for this study, I used the same Harvard Step for both male and female participants. Although use of the same step ensured uniformity, this may have contributed to the overall poor Harvard fitness score. In order to take regional population differences into account, several studies have readjusted the height of the Harvard step to cater for differences in gender and short stature [20, 21].
By utilizing a neutral examiner to examine OVC health outcomes and compare their ratings to a standardized tool such as the SF-36, this study is one of the first ones to examine how accurately OVC rate their health. If adequately powered and more biological outcomes such as HIV testing are included, studies similar to the one reported in this paper might obtain more generalizable results. These studies could provide future direction on whether the SF-36, could serve as objective screening tool for physical health of OVC and other adolescent populations.

In conclusion, this study found no differences in health outcomes among OVC in different living arrangements. The mean composite score for physical health on the SF-36 was above average. On 3 chosen physical health outcomes of hemoglobin, BMI, and the Harvard Step-test fitness score plotted against the SF-36 physical composite score, no correlations were noted. Although the SF-36 has been used on many other populations, this is among the first studies that have used it in a rural east African setting among adolescent OVC. Thus, this study provides a focal point for similar research. Next, it will be useful for policy makers to know what variables predict both the eight SF-36 scores, and the two summary composite scores for mental and physical health in adolescent OVC populations.
Appendix A: Health Examination Questionnaire

1) Date of Examination:
   Year: ___ / Month: ___ / Day: ___
   Or: DK / RF / MI (or strike across for NA)

2) Examinee:
   Or: DK / RF / MI (or strike across for NA)

3) Height (cm):
   Or: DK / RF / MI (or strike across for NA)

4) Blood Pressure (mm Hg):
   Or: DK / RF / MI (or strike across for NA)

5) Weight (kg):
   Or: DK / RF / MI (or strike across for NA)

6) Resting Pulse (beats per minute):
   Or: DK / RF / MI (or strike across for NA)

7) General Appearance:
   Mark one:
   a) Good
   b) Fair
   c) Poor
   Or: DK / RF / MI (or strike across for NA)

8) [If child wears glasses, please record vision while wearing glasses]
   Disjunct Vision:
   RIGHT
   Or: DK / RF / MI (or strike across for NA)

9) [If child wears glasses, please record vision while wearing glasses]
   Disjunct Vision:
   LEFT
   Or: DK / RF / MI (or strike across for NA)

10) Wears glasses?
    Mark one:
    a) Yes
    b) No
    Or: DK / RF / MI (or strike across for NA)

11) Hearing/Speaking Voice:
    RIGHT
    Mark one:
    a) Normal
    b) Abnormal
    Or: DK / RF / MI (or strike across for NA)

12) Hearing/Speaking Voice:
    LEFT
    Mark one:
    a) Normal
    b) Abnormal
    Or: DK / RF / MI (or strike across for NA)

13) HEAD
    Indicate whether "normal" or "abnormal" then make comments and record any history of sevenochronic injury/illness.
    Or: DK / RF / MI (or strike across for NA)

14) EYES, EARS, NOSE, THROAT
    Indicate whether "normal" or "abnormal" then make comments and record any history of sevenochronic injury/illness.
    Or: DK / RF / MI (or strike across for NA)

15) NECK
    Indicate whether "normal" or "abnormal" then make comments and record any history of sevenochronic injury/illness.
    Or: DK / RF / MI (or strike across for NA)

16) CHEST
    Indicate whether "normal" or "abnormal" then make comments and record any history of sevenochronic injury/illness.
    Or: DK / RF / MI (or strike across for NA)

Continue on next page →

5/17/2011 8:35 PM
17) ABDOMINAL
Indicate whether "normal" or "abnormal" then make comments and record any history of scars/chronic injury/illness.

Cr. EK / EF / MI (or strikes across for NA)

18) EXTREMITIES
Indicate whether "normal" or "abnormal" then make comments and record any history of scars/chronic injury/illness.

Cr. EK / EF / MI (or strikes across for NA)

19) [Items 19a-19d]
Boys only. Determine the child's testicular size.

Have you been circumcised?

- a) Yes
- b) No

Cr. EK / EF / MI (or strikes across for NA)

End of survey.
Appendix B: Child Health and SF-36 Questionnaire

132) During the past week, how many times did you eat a source of protein, such as eggs, milk, sausages, butterfish, lentils, chickpeas, soybeans, chicken, pork, lamb, mutton, pork, fish, or beef?
   ○ a) 0 times per week
   ○ b) 1 time per week
   ○ c) 2 times per week
   ○ d) 3 times per week
   ○ e) 4 times per week
   ○ f) 5 or more times per week
   [If > 5, skip question]
   [If < 3, skip question]
   [If 0, skip question]

133) Do you have any chronic medical conditions or disabilities?
   ○ a) Yes
   ○ b) No
   [If > 5, skip question]
   [If < 3, skip question]
   [If 0, skip question]

134) IF YES: What chronic medical conditions or disabilities do you have?
   [List conditions]

135) In the last 2 weeks, have you had any of the following?
   ○ a) Fever
   ○ b) Cough
   ○ c) Cold
   ○ d) Headache
   ○ e) Malaria
   ○ f) Diarrhea
   ○ g) Vomiting
   ○ h) Rash
   ○ i) Pain
   ○ j) Problems with vision
   ○ k) Problems with hearing
   ○ l) Fatigue
   ○ m) Sleepless nights
   ○ n) Night sweat
   ○ o) Injury
   ○ p) Other
   [List other conditions]
   [If > 5, skip question]
   [If < 3, skip question]
   [If 0, skip question]

136) In general, would you say your health is:
   ○ a) Excellent
   ○ b) Very good
   ○ c) Good
   ○ d) Fair
   ○ e) Poor
   [If > 5, skip question]
   [If < 3, skip question]
   [If 0, skip question]

137) Compared to one year ago, how would you rate your health in general now?
   ○ a) Much better now than a year ago
   ○ b) Somewhat better now than a year ago
   ○ c) About the same as one year ago
   ○ d) Somewhat worse now than a year ago
   ○ e) Much worse now than a year ago
   [If > 5, skip question]
   [If < 3, skip question]
   [If 0, skip question]

How TRUE or FALSE is each of the following statements for you?

Continue on next page →
POPO Round 8 P

138) I seem to get sick a little easier than other people.
   q.29m
   * Mask use:
   o a) Definitely true
   o b) Mostly true
   o c) Don't know
   o d) Mostly false
   o e) Definitely false
   Or: DE / RF / NA (or strikes across for NA)

139) I am as healthy as anybody I know.
   q.29n
   * Mask use:
   o a) Definitely true
   o b) Mostly true
   o c) Don't know
   o d) Mostly false
   o e) Definitely false
   Or: DE / RF / NA (or strikes across for NA)

140) I expect my health to get worse.
   q.29p
   * Mask use:
   o a) Definitely true
   o b) Mostly true
   o c) Don't know
   o d) Mostly false
   o e) Definitely false
   Or: DE / RF / NA (or strikes across for NA)

141) My health is excellent.
   q.29m
   * Mask use:
   o a) Definitely true
   o b) Mostly true
   o c) Don't know
   o d) Mostly false
   o e) Definitely false
   Or: DE / RF / NA (or strikes across for NA)

142) Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports.
   q.29n
   * Mask use:
   o a) Yes, limited a lot
   o b) Yes, limited a little
   o c) No, not limited at all
   Or: DE / RF / NA (or strikes across for NA)

143) Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf.
   q.29p
   * Mask use:
   o a) Yes, limited a lot
   o b) Yes, limited a little
   o c) No, not limited at all
   Or: DE / RF / NA (or strikes across for NA)

144) Lifting or carrying groceries.
   q.29m
   * Mask use:
   o a) Yes, limited a lot
   o b) Yes, limited a little
   o c) No, not limited at all
   Or: DE / RF / NA (or strikes across for NA)

145) Climbing several flights of stairs.
   q.29n
   * Mask use:
   o a) Yes, limited a lot
   o b) Yes, limited a little
   o c) No, not limited at all
   Or: DE / RF / NA (or strikes across for NA)

146) Climbing one flight of stairs.
   q.29p
   * Mask use:
   o a) Yes, limited a lot
   o b) Yes, limited a little
   o c) No, not limited at all
   Or: DE / RF / NA (or strikes across for NA)

147) Handing, grasping or creeping.
   q.29m
   * Mask use:
   o a) Yes, limited a lot
   o b) Yes, limited a little
   o c) No, not limited at all
   Or: DE / RF / NA (or strikes across for NA)

148) Walking more than one kilometre.
   q.29n
   * Mask use:
   o a) Yes, limited a lot
   o b) Yes, limited a little
   o c) No, not limited at all
   Or: DE / RF / NA (or strikes across for NA)

Continue on next page →
24)

149) Walking several hundred meters.

Mark one:  
- a) Yes, limited a lot.  
- b) Yes, limited a little.  
- c) No, not limited at all.  

0r. OK / RF / MI (or strike across for NA)

150) Walking one hundred meters.

Mark one:  
- a) Yes, limited a lot.  
- b) Yes, limited a little.  
- c) No, not limited at all.  

0r. OK / RF / MI (or strike across for NA)

151) Bathing or dressing yourself

Mark one:  
- a) Yes, limited a lot.  
- b) Yes, limited a little.  
- c) No, not limited at all.  

0r. OK / RF / MI (or strike across for NA)

Child Health Past 4 Weeks

152) How many days have you been sick during the past 4 weeks?

Mark one:  
- a) All of the time  
- b) Most of the time  
- c) Some of the time  
- d) A little of the time  
- e) None of the time  

0r. OK / RF / MI (or strike across for NA)

During the past four weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

157)

Cut down the amount of time you spent on work or other activities?

Mark one:  
- a) All of the time  
- b) Most of the time  
- c) Some of the time  
- d) A little of the time  
- e) None of the time  

0r. OK / RF / MI (or strike across for NA)

Accomplished less than you would like?

Mark one:  
- a) All of the time  
- b) Most of the time  
- c) Some of the time  
- d) A little of the time  
- e) None of the time  

0r. OK / RF / MI (or strike across for NA)

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159) Did work or activities less carefully than usual?  
    - Did you feel full of life?  
    - How much bodily pain have you had during the past 4 weeks?  
    - During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?  
    - Did you have a lot of energy?

Survey ID: __ __ __ __

160) During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?  

161) Have you been a very nervous person?  

162) Have you felt so down in the dumps nothing could cheer you up?  

163) How much bodily pain have you had during the past 4 weeks?  

164) Have you felt so down in the dumps nothing could cheer you up?  

165) Have you felt calm and peaceful?  

166) Have you felt calm and peaceful?

167) Did you have a lot of energy?

These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks?
168) Have you felt downhearted and depressed?

- Most of the time
- Some of the time
- A little of the time
- None of the time

Or: DK / NA / (for strikes across for NA)

169) Did you feel worn out?

- Most of the time
- Some of the time
- A little of the time
- None of the time

Or: DK / NA / (for strikes across for NA)

170) Have you been a happy person?

- Most of the time
- Some of the time
- A little of the time
- None of the time

Or: DK / NA / (for strikes across for NA)

171) Did you feel tired?

- Most of the time
- Some of the time
- A little of the time
- None of the time

Or: DK / NA / (for strikes across for NA)

172) During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting friends, relatives, etc.)?

- Most of the time
- Some of the time
- A little of the time
- None of the time

Or: DK / NA / (for strikes across for NA)
Appendix C

I. Duke IRB approval

IRB NOTIFICATION OF CONTINUING REVIEW APPROVAL

Continuing Review ID: CR_4_Pen00006633
Principal Investigator: Kathryn Whetten
Protocol Title: Positive Outcomes for Orphans
Sponsor/Funding Source(s):
Elton John AIDS Foundation
National Institute of Child Health and Human Development
Federal Funding Agency ID: R01HD045345-06A1
Date of Declared Conformance with federally funded grant, if applicable: N/A

The Duke University Health System Institutional Review Board for Clinical investigations has conducted the following activity on the study cited above.
Activity: Continuing Review
Review Date: 3/1/2011
Issue Date: 3/1/2011
Anniversary Date: 2/27/2011
Expiration Date: 2/27/2012

DUHS IRB approval encompasses the following specific components of the study:
Protocol, version/date: --
Summary, version/date: 12/24/10
Consent form reference date: --
Investigator Brochure, version/date: --
Pediatric Risk Category: 45 CFR 46.404 and 21 CFR 50.51 as applicable
Other: --

The DUHS IRB has determined the specific components above to be in compliance with all applicable Health Insurance Portability and Accountability Act ("HIPAA") regulations.

This study expires at 12 AM on the Expiration Date cited above. At that time, all study activity must cease. If you wish to continue specific study activities directly related to subject safety, you must immediately contact Dr. John Palfi or Jody Power. Continuing review submissions (measuds) must be received by the DUHS IRB office 60 to 45 days prior to the Expiration Date.

No change to the protocol, consent form or other approved document may be implemented without first obtaining IRB approval for the change. Any proposed change must be submitted as an amendment. If necessary in a life-threatening situation, where time does not permit your prior consultation with the IRB, you may act contrary to the protocol of the action is in the best interest of the subject. You must notify the IRB of your action within five (5) working days of the event.

The Duke University Health System Institutional Review Board for Clinical Investigations (DUHS IRB), is duly constituted, fulfilling all requirements for diversity, and has written procedures for initial and continuing review of human research protocols. The DUHS IRB conforms with all U.S. regulatory requirements relating to the protection of human research participants. Specifically, the DUHS IRB complies with 45 CFR 46, 21 CFR 50, 21 CFR 56, 21 CFR 312, 21 CFR 312, and 45 CFR 164.508-514. In addition, the DUHS IRB complies with the Guidelines of the International Conference on Harmonization to the extent required by the U.S. Food and Drug Administration.

DUHS Institutional Review Board
2424 Erwin Rd Suite 405 Durham, NC 27713 919.689.5111
Federalwide Assurance No. FWA 00000035

27
II. KEMRI IRB Approval

KENYA MEDICAL RESEARCH INSTITUTE

KEMRI/RES/1/3/1

May 9, 2011

TO: AUGUSTINE IMBUYE WASONGA (PRINCIPAL INVESTIGATOR)
ACE AFRICA -KENYA
P. O. BOX 1185-50200,
BUNGOMA

Dear Sir,

RE: NON-SSC PROTOCOL No. 278 – REvised (RE-SUBMISSION): POSITIVE OUTCOMES FOR ORPHANS (POFO II) (VERSION DATED 3 MAY 2011)

Reference is made to your letter dated May 3, 2011.

We acknowledge receipt of the revised consent documents and the baseline findings for the initial POFO study.

The Committee is satisfied that the issues raised at the initial review have been adequately addressed.

Authorization is granted for implementation of the study effective this 9th day of May 2011. Please note that authorization to conduct this study will automatically expire on 7th May 2012.

If you plan to continue with data collection or analysis beyond this date, please submit an application for continuing approval to the ERC Secretariat by 26th March 2012.

Any unanticipated problems resulting from the implementation of this protocol should be brought to the attention of the ERC.

You are also required to submit any proposed changes to this protocol to the SSC and ERC prior to initiation and advise the ERC when the study is completed or discontinued.

Sincerely,

Christine Wasunda,
FOR: SECRETARY,
KENRI/NATIONAL ETHICS REVIEW COMMITTEE
III. KCMC IRB Approval

CRERC FORM 07

TUMAINI UNIVERSITY
KILIMANJARO CHRISTIAN MEDICAL COLLEGE
P. O. Box 2249, MOSHI, Tanzania
RESEARCH ETHICAL CLEARANCE CERTIFICATE
No. 026

Research Proposal No. 076

Study Title: POSITIVE OUTCOME FOR CHILDREN ORPHANED BY AIDS IN CULTURALLY DIVERSE COUNTRIES

Study Area: KILIMANJARO

P. I Names: DR. MOHAMMED

Institution(s): KILIMANJARO CHRISTIAN MEDICAL COLLEGE AND DURKE UNIVERSITY

The Proposal was approved by 11th AUGUST 2005

Duration of Study: FROM 30TH SEPTEMBER 2011 TO 30TH SEPTEMBER 2012

Name: DR. ATENG O. TEMBA
Signature: ____________________________
Research Administrator – CRERC

Name: PROF. FRANKLIN W. MOSHA
Signature: ____________________________
Chairman – CRERC
Appendix D: Consent Forms

I. In English

DUKE UNIVERSITY HEALTH SYSTEM

Consent To Participate In A Research Study
Positive Outcomes for Orphans

PURPOSE:
You are the adult who has lived with children. The legal guardian for children participating in this study will be the parent or legal guardian, or as designated by the parent or legal guardian. The purpose of this research study is to test new interventions for children in both community-based care and institutionalized care transition to adulthood and young adulthood. The results of this study will be used to improve outcomes for children in foster care and orphaned children, their families, and their communities.

DURATION:
The interview and evaluation for the child will last about 30 minutes, and the interview for you, the caregiver of the child, will last for about 30 minutes. This is a longitudinal study, which makes we will return to interview you and the child again with some of the same and some different instruments in 1 year, 2 years, 3 years, and 4 years from now.

PROCEDURES:
If you agree to let the child be part of this study, you will be asked to respond to questions about your health, your personal behaviors, your household living situation, and your relationship with the child. The data collection will include data on the child's health, ability to complete tasks from a model, and ability to solve problems with pictures. For children aged 10 years old, we will ask the child questions about health, behaviors, experiences, beliefs, mood, physical and pneumonia health, school attendance and performance, income earnings and work activities, and reports of partners, HIV testing, and drug use. The interview will be conducted by a research assistant on a computer. If you choose to, your legal guardian, have the right to be with the child for the duration of the interview.

For children aged 10 years and older we will perform a one-time physical exam, and the child will be asked to engage in physical activity for 5 minutes in order to measure cardiovascular health. Some blood (less than 5 ml) may be collected with your consent and sent either to a local lab or a laboratory in the United States for analysis to determine whether detectable levels of HIV-1 RNA-2, which may be a risk factor for developing HIV. As part of the physical examination, a very small amount of blood (less than 1 ml) may also be collected and analyzed immediately to check the levels of certain types of blood cells (called hemoglobin) in your child's body.

RISKS AND DISCOMFORTS:
There are no known risks to participate in the study. Some of the questions may make you or the child feel uncomfortable, and there are no questions about the child who has died. The interviewers are trained to help you or the child, if needed, and the questions are worded in a way that is easy to understand. The interviewers are also trained to help you, the child, or the legal guardian, if you have any questions that come up in the interview with the interviewer or another community person. In addition, you or the child can refuse to answer any questions, and you or the child can ask that the interview be stopped at any time. There are no negative outcomes for meeting that the interview be stopped.

There is no risk to your health from the finger prick or blood draw (for children aged 10 years or older only), and the techniques and equipment are always used. Some people experience mild discomfort from the finger prick or blood draw, which usually subsides after the procedure is done.

PROCEDURE: PROVIDER

Consenting Reviewer: D.M. 719/06/12

Reference Date: 11/28/2012

Page 1 of 5

Parent/Consentee Initials: __________________________
DUKE UNIVERSITY HEALTH SYSTEM

Consent To Participate In A Research Study
Needless Intrasonography for Orphans

BENEFITS:
There are no direct benefits to you, the orior, or the legal guardian, for participation in this study. However, knowledge gained from this study may contribute to providing the best care for children who have been orphaned as well as the needs of their caregivers.

CONFIDENTIALITY:
Protecting the confidentiality and privacy of study participants is very important to us. Every effort will be taken to protect the identity of the participants in the study. This means we will make sure that neither your name nor the child’s name is ever published or released along with your specific answers to survey questions. When we publish the results of this study, it will be impossible to identify any single person from our results. Only with the legal guardian’s written permission will the child’s name be used. The names of individual interviews with parents, however, there is no guarantee that the information cannot be obtained by legal process or court order.

To reduce the likelihood that your identity and answers are ever released by accident, we take the following measures:
- You and the orior have both been assigned a number called a “Study ID number.” This Study ID number is used instead of your name or medical study name and record. Only necessary study personnel at [organization] and at Duke University have your Study ID number, and your Study ID number is the only link between your name or other identifying information and your answers to the survey questions.
- We will never use your name, the child’s name, or other identifying information on the same page as your answers to survey questions.
- We will never store or keep track of your name, the child’s name, or other identifying information with your answers to survey questions.
- We will store all completed surveys at [organization] in locked cabinets, and only approved study personnel will have access to those cabinets. We will store all contact forms with both your name and Study ID number in a separate locked cabinet. All electronic study data will be stored securely (encrypted and password-protected) with access restricted to study personnel.

When the information or data from the interviews is sent to the U.S. for analysis, it is sent without your or the child’s name. In the U.S., we will store all the information in a locked office. Copies of the contact forms, with your and the child’s name and the Study ID number, will be sent separately to Dr. Whelan and will be stored in a separate locked cabinet.

Sometimes, there are future studies where the information you give us about your or the child’s name. In the U.S. we will store all the information in a locked office. Copies of the contact forms, with your and the child’s name and the Study ID number, will be sent separately to Dr. Whelan and will be stored in a separate locked cabinet.

FINANCIAL COST OF RESEARCH:
There is no cost to you, the legal guardian, for participation in the study.

PAYMENTS TO PARTICIPANTS:
There are no payments for participation.

ETHICAL CLEARANCE:
Ethical clearance for this study has been obtained by Duke University and [organization] named.

Protocol ID: Pro1234567
Continuing Review Date: 02/06/2013
Reference Date: 07/12/2014
Page 2 of 5
Parent/Guardian Initials: __________________________
RIGHT TO REFUSE:
Your participation in this study is voluntary, which means you, or the child, don't have to do it if you don't want to. You can stop at any time without penalty. You may also refuse to answer any of the questions. If you feel you have any questions, you may contact [legal interviewer at name], [organization director at organization], [name], or the Duke Researchers directly at +1-813-813 8500.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?
For questions about your rights as a research participant, contact Duke University Health System Institutional Review Board (IRB) Offices at +1-813-813 4111.

SUBJECT’S AGREEMENT:
I give permission for a finger-stick test to be performed to look at levels of blood tests and look for antibodies for herpes simplex virus type 2 (HSV-2).

____ Yes  ____ No  ____ Initials

I give permission for blood (up to 6 ml) to be drawn and sent to a local lab or to a lab in the United States to look for antibodies for herpes simplex virus type 2 (HSV-2).

____ Yes  ____ No  ____ Initials

I give permission for staff associated with Duke University and its partner organizations to contact me for other studies in the future.

____ Yes  ____ No  ____ Initials

"I have read or had read to me the information provided above. I voluntarily agree to participate in this study and that the data may be utilized by Duke University for possible future studies. After it is signed, I understand I will receive a copy of the consent form.

Signature of the child (bracket)  Date__________________

Name of child ____________________________

Signature of caregiver (legal guardian)  Date__________________

Name of caregiver (legal guardian) __________________________________________________________________________

Signature of person obtaining consent  Date__________________

Name of person obtaining consent ____________________________________________________________

Protocol # [Redacted]  Reference Date 9/7/2012

Page 1 of 5  Parent/Guardian Initials ____________
II. In Swahili

Tunako la Ridhasa/akabaliana kwa usaliti
Matokeo Mazuri kwa aji kwa wadogo ya yasema

MADHUKUMU:
Wewe anezo alichagua naye maelezo mazoechi kwa kihisi kati si wewe wa usaliti

MUDA:
Usaliti za ufisahisi zimezara kwa mtoto utakusuka kati daika 120, na wakati wa kusalatia wa usaliti utakusuka kwa daika 49.

UTARATIBI:
Ikawa utakubali wewe na mtoto mchakini kwa kati kia uchungaji, kwa masaa hiyo tutakusuka sawa na mtoto mara mara kwa masawili haya haya anyeshe na macheo la kihisi la vitendo vya kati ya masaa 1, Masaa 2, Masaa 3, na Masaa 4 kutoka mwezi.

TAWREF, wewe kama mke wewe na mtoto mchakini utawezesha kawusu kwa mtoto watani naye (POPO) 1, tabia ya mchakini mwingine na tabia ya vitendo vya kati ya masaa 1 na Masaa 2, na mchakini mwingine na tabia ya vitendo vya kati ya masaa 3 na Masaa 4.
Tanzisko la Rubaha/Rubabika kwa ustawizi
Matookeo Mzuri kwa ajili ya wazito yataifa

cherchevemente za kinga muwili hupesa simplex type 2 (HSV-2), ambazo zinawasa kwa zahabu ya betari ya kusambukiza HIV. Kama sahihi ya uchadjiriwa wa afya kimetoa, kiasi kidogo cha demi kidego zona (chiki ya limu) inawezekana pia kusamahwa na kugathika mara tu ili kapidha vilewogo vyw sana nyungani ya cherchevement wa dama (umoyovu hawa) ndani ya mamlili wa neste wako.

HATARI

Tamu la Ridiheza/akubaliwa kwa ustafiri
Matokeo Mazuri kwa ajili ya watoto watatu

Nambari yako ya utafiti na nambari yako ya utafiti ndilo utafuata to lia ya jina lako au utambulisho wa habari na majibu yako ya dodoo la maelewili.

- Hata mwen endika jina lako, la moto au habari nyuma ya yoyote ya utambulisho kwendo Ukonza inawezekana kwa majibu yako ya dodoo la maelewili.
- Hata mwen endika jina lako, la moto au habari nyuma ya utambulisho ya majibu yako ya dodoo la maelewili.

- Tuta kihisi fama kizito za ridha ai afaka anaa kwenye kabiri la liko. Liko na TAWREEF na mwanayaki aleye kizito wa ndogo siku pekikabali kwendo kihisi au kihisi la liko. Tuta kihisi fama kizito za ridha za kihisi na kihisi za liko ya jina lako na jina la maelewili ya habari yako ya dodoo la maelewili.

Watapi babari bizi as data kutoa kwa haya sababisho inawezekana kwa habari wa uchambuzi au maelewili. Watapi babari bizi as data kutoa kwa haya sababisho inawezekana kwa habari wa uchambuzi au maelewili.

Nakala za fama za ridha za jina lako au maelewili za habari za utambulisho za ustafiri za fama za ustafiri la maelewili.

Harama za Utapiti:
Hakuna gharana kwako au moto moto kwa kushiriki kuhusu kuzitaji.

Mali po Kwa WASHIRIKI:
Hakuna mali po yoyote Kwa kushiriki.

Kirali cha Utapiti:
Kibali cha utafiti huku kinachotua na chao chwaa cha Duke na NIMRI pamoja na KCMC.

Haki ya Kukataa:

Nani Nimpigir Simu: Kama Nina Maswali Au Matatizo?

Protocol ID: Precio008533
Ordering Institution Name: BZ252612
Reference Date: 8/12/2011

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Parent/Guardian Initials: 
Kwa muhimamu huku siko kama mchakushi wa usalama, wasiliana na Duke University Health System Institutional Review Board (IRB) Ofisi kwa +1-919-668-3111.

KIBALI CHA MCHAKUSHI:
Napongeza ruhoga kwa neno kwamba kidole kuungalia viwango vya uheshimisho za daruo na kuungalia zime ya virioni vya 2 (HSV-2):

_________ Ndio ... Hapana ... Horufu ya jinsi

Napongeza ruhoga ya kuatua duuma (tuuki 5 ml) na isipokuwa kwamba wasiliana wa mahubu iliyosaidia ili twawe kupatwa na kuhamishia wapokuwa ha virioni vya HSV - 2:

_________ Ndio ... Hapana ... Horufu ya jinsi

Napongeza kiwanda kwa wakimbizi wa idadi ikina chis Duke kwasiliwa sawa na vikati wa:

_________ Ndio ... Hapana ... Horufu ya jinsi

References


20. Stephenson, L.S., et al., *Physical fitness, growth and appetite of Kenyan school boys with hookworm, Trichuris trichiura and Ascaris lumbricoides*


