THE EFFECT OF THE BASIC CARE PACKAGE ON MORBIDITY AMONG HIV/AIDS PATIENTS SEEN AT MILDMAY UGANDA

By

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DECLARATION

I, Faith Nakiyimba declare that this thesis has never been presented to any institution of higher learning here or abroad and the work contained in it, is original unless otherwise stated.

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DEDICATION

I dedicate this book to my beloved husband Charles and children; Joy, Joel and Jeannette for the support, love, patience and care they rendered to me.

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How does some one-say ‘thank you’ when there many people to thank. Special gratitude goes to Dr Nazarius Mbona Tumwesigye and Dr Juliet Babirye for their incredible support and deep insights in the original conception of this thesis.

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ABREVIATIONS/ACRONYMS

AIDS ……Acquired Immunodeficiency Syndrome

BCP……. Basic Care Package

CDC…… Centre for Disease Control and Prevention

HIV……...Human Immunodeficiency Virus

ITNS…… Insecticide Treated Nets.

MOH…… Ministry of Health

PACE……Programme for Accessible Health Communication and Education

PSI…… Population Service International

VCT……. Voluntary counselling and Testing

WHO…… World Health Organization

UNAIDS…….. The Joint United Nations Programme on HIV and AIDS

OPERATIONAL DEFINITIONS

Morbidity = fever, malaria or diarrhoea related morbid events

- Fever defined as a record of a temperature of ≥37.5°C.
- Malaria defined as a temperature of ≥37.5°C, final the diagnosis (primary outcomes) based on reported symptoms, observed signs, and the results of laboratory investigations if any.
- Diarrhoea defined as record of loose motions ≥3 times a day plus laboratory findings if any.

Utilization was defined as bed net hanging over sleeping area, water vessel containing water and bottle of water guard having been opened or empty

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ABSTRACT

Introduction: There are inexpensive interventions incorporated into the HIV basic care package, which have proven to be effective in reducing morbidity among persons with and without HIV.

Objective: To assess the effect of the basic care package on morbidity among HIV persons seen at Mildmay Uganda in order to justify further distribution among HIV infected persons.

Methods: A retrospective cohort study involved secondary analysis of 148 case notes of persons who received the basic care package. A survey on same population assessed possession and utilization of the package. Out come was determined by difference in mean episodes of fever, malaria and diarrhoea related morbidity 12 months before and after receiving package and frequency among utilizers and non utilizers.

Findings: After receiving the package, there was no significant difference in mean episodes of fever, [-0.13, 95% CI =-0.12-0.38] and malaria, [-0.14, 95% CI =-0.17-0.46] related morbidity. Neither was the increase noted in diarrhoea related morbidities, [+0.53, 95% CI =-0.19-0.08] significant. Bed net utilization showed significant reduction in fever and malaria related morbidity,[χ , p value = 14.96,0.001 and 18.78,0.0009] respectively.However,safe water vessel utilization showed no significant reduction in diarrhoea related morbidity, [χ, p value =1.41, 0.23]. A bed net was hanging over sleeping area in 82 percent, vessel containing water in 33 percent and water guard® bottle having been opened in 9 percent.

Conclusion: *The basic care package had no significant effect on fever, malaria and diarrhoea related morbidities among HIV infected persons attending Mildmay Uganda.*

Recommendation: A detailed prospective study involving urban and rural populations or a retrospective study among persons who remained ART naïve for one year after receiving the

package would address this study question. An in depth survey to assess why the safe water system was poorly utilized would be important

CHAPTER ONE

BACKGROUND TO THE STUDY

INTRODUCTION

Globally, almost 40 million people now live with HIV/AIDS (UNAIDS 2004).Of this estimated 40 million persons living with HIV, 95 percent live in resource-poor countries where access to basic health care, adequate nutrition and water are severely limited (WHO, 2005). The HIV pandemic has dramatically changed patterns of disease in developing countries with previously rare "opportunistic" diseases becoming more common. High rates of mortality due to endemic conditions such as diarrhoeal diseases, malaria and wasting syndromes (Brink *et al,* 2001, et al, 1997,Kaplan and Grant *et al,* 1996, Francesconi *et al,* 2001, French *et al,*2001,Whitworth e*t al,*2000),which were formerly confined to the elderly and malnourished, are now common among HIV infected young and middle-aged people in many developing countries (U.S. Department Health and Human Services 2003).Environmental issues such as tropical infections, poor living conditions, and limited access to safe drinking water and sanitation facilities increase the risk of infections in HIV persons.

Fever is one of the most frequent symptoms reported by HIV-infected individuals and is seen in nearly 97 percent of patients with symptomatic primary HIV infection (Holtzclaw, 1998). Fever is a physiologic defence that has both detrimental and beneficial effects, particularly in persons with HIV infection. In HIV disease, fever often signals the onset of an opportunistic infection, a condition that is considered a crisis (Jones 1993). Fever may occur with infectious or iatrogenic causes such as throat, respiratory or urinary tract infections, malaria, gingivitis, gastroenteritis, and drug interactions. HIV infection lowers the specificity of a fever-based malaria case

definition and this makes it difficult to investigate for the interaction between malaria and HIV (Holtzclaw .J Barbara, 1998). In other words, the higher the prevalence of HIV in a population, the lower the probability that a person with fever has malaria. In areas with a generalized HIV epidemic, this may result in over diagnosis of malaria and overuse of anti-malarials.

Studies that evaluated the effect of HIV-1 infection on malaria incidence, have provided strong evidence for an increased risk of malaria among HIV-positive (Cohen, 2005, Francesconi et *al,* 2001, French *et al, 2*001, Whitworth e*t al,* 2000). This is supported by findings of a prospective study that assessed the effect of cotrimoxazole on morbidity, mortality, CD4 cell count and viral load in HIV infected persons in rural Uganda which showed that malaria was 1.7 times (95%CI = 1.1-2.5) more common among HIV infected individuals less than five years of age and 2.6 times (95% CI =1.9-3.6) in those above five years, than their negative counterparts (Mermin *et al,* 2004.

Prevention of malaria in HIV infected persons is increasingly regarded as part of their basic care (Whitworth &Hewitt, 2005).Therefore, to improve the clinical and public health strategies to prevent malaria, identification of the best methods for reducing the incidence and a better understanding of the relation between HIV disease are key (Kerenromp *et al*, 2005). Prophylaxis with cotrimoxazole (trimethoprim and sulfamethoxazole) and use of insecticide treated mosquito nets (ITNs) have proven to reduce the incidence of malaria, as well as mortality, in HIV-infected people in Africa (Anglaret *et al,* 1999, Hawley *et al,* 2003, Lengeler, 2004 Mermin *et al*, 2004, Mermin *et al*, 2006a, Ter Kuile 2003a, 2003b).

Diarrhoea affects 90 percent of persons living with HIV (Katabira, 1999; Monkemuller and Wilcox 2000). Diarrhoea is four times (IRR = 3.6, 95% CI =2.2-6.0, p=0.0001) more common among children with HIV and seven times (IRR = 7.0, 95% CI= 5.4-9.2, p= 0.0001) more common among adults with HIV than their HIV-negative counterparts (Mermin *et al*, 2004). An increased risk of diarrhoea is attributed to poor water storage. Regardless of where or how the water is collected, storage vessels with wide openings such as pots or buckets are easily contaminated with faeces, through the introduction of cups, dippers, or hands. Flies, cockroaches, and rodents might also contaminate water (Knight *et al*, 1992). The risk of diarrhoea through water treatment with sodium hypochlorite solution, safe water storage, and behaviour change techniques that is a household-based intervention is greatly reduced (Luby 2004, Lule *et al*, 2005, Quick 1996, 2002). Cotrimoxazole has also proven to reduce the risk of diarrhoea (Lule e*t al,* 2005).

Although antiretroviral treatment prolongs lives, winning the war against the pandemic demands a combination of, medicine, food, and clean water to make the treatment successful (Lee Jongwook, 2003). Besides, the estimated annual cost of basic care and treatment for a person with HIV/AIDS (not including the costs of antiretroviral therapy) is as much as two to three times the annual per capita gross domestic product in developing countries (UNAIDS 2002). Yet the annual per capita income is typically less than US$200, and annual per capita health expenditure is below US$10 (Human development report 1991).

With malaria, diarrhoea and HIV infections being endemic and responsible for significant morbidity and mortality, high impact, evidence based interventions that prevent these diseases

are very important and should be integrated into patients' care whether or not antiretroviral treatment is available. In response, PSI, currently known as Programme for Accessible Health Communication and Education (PACE) and the United States (US) centres for disease control and prevention (CDC), in collaboration with Ministry of Health (MOH) and other local partners, have worked together to develop the basic care package.

Several studies, conducted in research settings, have evaluated the effect of the different components of the basic care package. These studies have come up with encouraging results for incorporating these components into HIV/AIDS treatment (Mermin *et al*, 2005, Lule *et al*, 2005, Watera *et al*, 2006), but, there is limited information about this effect at service delivery environments.

CHAPTER TWO
LITERATURE REVIEW

2.1 Introduction

This chapter presents findings of various studies that evaluated the effect, and utilization levels of the different interventions that have proven to be effective against malaria and diarrhea, (i.e cotrimoxazole, insecticide treated nets, and the safe water system).

2.2 Preventive measures

Effect of Cotrimoxazole on morbidity

Cotrimoxazole prophylaxis is recommended as part of the essential care and support package for symptomatic HIV-infected individuals in sub-Saharan Africa (UNAIDS, 2000, WHO, 2006). This was supported by several studies that showed significant beneficial effects of cotrimoxazole on death and no significantly greater risk of adverse effects among people with early and advanced HIV disease (Anglaret *et al*, 1999, Grimwade *et a l*, 2003, Wiktor *et al*, 1999). Good examples of cotrimoxazole beneficial effects on the morbidity were reported by a study that assessed effect of cotrimoxazole prophylaxis on morbidity, mortality, CD4-cell count, and viral load among infected persons attending TASO, Uganda. In that study, cotrimoxazole reduced the incidence of: malaria by 72 percent (IRR = 0.28, CI = 0.19-0.40) and diarrhoea, by 35 percent (IRR =0·65, CI =0·53—0·81]). Cotrimoxazole was also reported beneficial, on malaria incidence even in areas of high bacterial resistance in a study that assessed the feasibility and effectiveness of cotrimoxazole prophylaxis for HIV-1-infected adults (Watera *et al*, 2006). Cotrimoxazole prophylaxis among persons with HIV was associated with fewer diarrhoea

episodes [0.9 versus 2.0 episodes per person-year; [^{IRR} = 0.42, 95% CI = 0.34–0.51, $P < 0.0001$] (Lule *et al,* 2005).

Effect of Insecticide treated nets (ITN) on morbidity

Malaria seems to be more severe in HIV infected adults than in people without the virus. For example, a case control study conducted in Luanshya, Zambia that set out to determine whether HIV infection and HIV related immunosuppression were risk factors for severe malaria in adults, showed that HIV infection was a highly significant risk factor for adults with severe malaria compared with controls with uncomplicated malaria (OR= 12.6, 95%, CI = 2.0–78.8; Chalwe *et al,* 2009). A prospective cohort study in South Africa which evaluated whether HIV infection increased the risk of severe malaria in adults from both areas of stable and unstable transmission, reported that, the non-immune HIV-infected patients were significantly more likely to have severe clinical malaria than were non-immune patients without-HIV, (OR = 4.15, 95% CI 1.57-10.97; Cohen 2005).The severity and the increased risk of having malaria in HIV infected persons could be supported by the fact that malaria is associated with a rise in HIV viral load (Kublin *et al,* 2005), and a fall in CD4-cell count which in the long run, potentially worsens the clinical course of people with HIV infection (Korenromp et *al*, 2005). Malaria was 29% less frequent per 100-cell/mm^3 increase in CD4 cell count (RR=0.71,CI =0.51-0.99,p=0.04; Mermin *et al,* 2006).

The high incidence and potentially poor outcomes of malaria among people with HIV supports use of insecticide treated nets in HIV-infected populations (Korenromp, 2005; Kublin, 2005; Mermin, 2006b; Patnaik, 2005; Whitworth, 2005). For a long time, insecticide-treated mosquito nets have been known to be one of the main cost-effective and sustainable community-based

malaria vector control tool against malaria and are strongly advocated for malaria prevention (Lengeler *et al,* 1996, Zaim *et al,* 2000). This could be explained by findings of better humoral immune response among those who had utilized impregnated bed nets than among those who had not, in a study that assessed efficacy of permethrin-impregnated bed nets on malaria control in a hyper endemic area in Irian Jaya, Indonesia (Sutanto *et al,* 1999).

The justifiable role of insecticide treated nets in the control of malaria-related mortality has been more among children living in the sub Saharan Africa (Alonso *et al,* 1999, Binka *et al,* 1996, D'Allesandro *et al,* 1995, Froebel *et al* 2004, Moore *et al,* 2000, Xiao *et al,* 1998) and among pregnant women (Ladner 2003).Studies assessing the impact of insecticide treated nets have also been conducted among HIV infected populations. Among HIV infected children, a 43 percent (IRR =0.57, 95% CI, 0.46–0.71,P<0.001) reduction in the incidence of malaria was observed in a prospective cohort study that evaluated the effect of trimethoprim-sulfamethaxazole and insecticide treated bed nets on malaria among HIV infected children (Kamya *et al,* 2007).Studies that have evaluated the effectiveness of bed nets in adult populations have given similar results in both non -HIV infected (Lengeler, 2004; Ter Kuile, 2003) and in HIV infected persons; for example a study that evaluated the additive effect of cotrimoxazole, anti retroviral therapy and bed nets on frequency of malaria in HIV persons in TASO Tororo, showed substantial reductions of 95 %,IRR = 0.05, CI= 0.03-0.08,p =<0.0001;Mermin *et al*, 2006) but these studies were conducted in research settings.

Some studies have investigated the operational effectiveness of bed nets (D'Alessandro *et al.,* 1995, Guyatt *et al,* 2002, Maxwell *et al,* 2002, Schellenberg *et al,* 2001, Spencer *et al,* 2004) in

non HIV populations. An example is a survey that evaluated an insecticide-treated bed net distribution programme among non –HIV persons in camps for internally-displaced persons in Western Uganda which showed a reduction in malaria episodes among bed net utilizers, (RR = 0.63, 95%,CI =0.46—0.87)when compared with non-utilizers . However, uncertainties still remain about the effectiveness of insecticide treated nets when implemented on HIV patients in operational environments.

Water safety

The important role of sanitation and safe water in maintaining health has been recognized for centuries, with the 'sanitary revolution' in the 19th and early 20th century. The Joint Monitoring Programme for Water Supply and Sanitation estimates 1.1 billion people live without improved water sources, while over half of the developing world population representing 2.6 billion people lack access to improved sanitation (WHO/UNICEF, 2005). WHO data on the burden of disease suggests that, approximately 3.2 percent of deaths, 4.2 percent of disability adjusted- life years (DALYs) and 88 percent of diarrhoeal diseases, of the 61.9 million cases worldwide, are attributable to unsafe water, sanitation and hygiene (WHO, 2004). Diarrhea accounts for nearly 1.6 million deaths and 15 percent of under-five mortality, each year in developing countries (WHO 2002). In sub-Saharan Africa, diarrhoea is an important cause of morbidity and mortality in people living with HIV, (Kaplan *et al*, 1996, Grant *et al*, 1997, Brink *et al*, 2002).

There multifactorial interventions consisting of water supply, sanitation and hygiene education which reduce the risk of diarrhea but are not more effective than individual interventions (Fewtrell &Colford, 2004). Evidence is now conclusive that simple, low-cost strategies for safely

treating and storing water at the household level can greatly improve the microbial quality of water and result in diarrheal disease morbidity reductions comparable to those achieved by interventions that promote personal and domestic hygiene; hand washing and safe feces disposal (Curtis & Cairncross, 2003, Huttly *et al.*, 1994, Sobsey, 2002, WHO, 1993).

Interventions that targeted only the water source, showed a lesser risk reduction when compared with risk reduction with the point-of-use treatment (Fewtrell and Colford , 2004, Wright *et al.*, 2004). For example, a systematic review and meta- analysis of water, sanitation, and hygiene interventions and their impact on diarrhoea in less developed countries showed that water supply interventions were 25 percent effective in reducing diarrheoa episodes (RR =0.75, 95% 0·62–0.91) when compared with 39 percent (RR = 0·61, 95% CI =0·53–0·89) seen with the point of use treatment (Fewtrell and Colford, 2004).The point of use treatment can be achieved by providing people with simple affordable technologies such as chlorination, filtration, solar disinfection and improved storage in their homes (The Cochrane Collaboration 2003). A systematic review and meta-analysis of ten studies which evaluated the impact of treating water with chlorine at point-of-use on water quality and incidence of diarrhoea among children in developing countries, showed that that point-of-use treatment of drinking water with chlorine reduces diarrheoa episodes in children, by 29 percent (RR= 0.71; 0.58–0.87; Arnold and Colford, 2007).

The Safe Water System (SWS) (CDC, 2000) is a household-based water quality intervention that has been shown to reduce risk of diarrhoea through treatment of water with sodium hypochlorite solution, safe water storage, and behaviour change techniques (Luby, 2004; 2002Quick, 1996).

Source: safe water system Lule *et al*, 2005

The safe water system. It is composed of a 20-liter polyethylene vessel with a spigot that prevents recontamination, a bottle of 0.5% sodium hypochlorite solution, and a locally produced cloth. Twenty litres of water are poured through the cloth into the vessel and one or two capfuls (equivalent to 10–20 ml) of sodium hypochlorite solution are added for disinfection.

Water chlorination and storage in a special container with a narrow mouth, reduced episodes of diarrhea by 43 percent in Bolivia, in a non-HIV population (Sobsey Handzel and Venczel, 2003). A similar evaluation has been done among persons with HIV in a research setting in TASO, Uganda, which showed a lesser but significant reduction of 25 percent (IRR = 0.75, 95% CI = 0.59–0.94, $P = 0.015$). There is need to do an evaluation of the effect of the safe water system on diarrhea episodes among HIV infected persons in service delivery environments.

Antiretroviral therapy (ART)

Antiretroviral therapy has changed HIV infection from a debilitating fatal disease to a chronic manageable disease, although, HIV related opportunistic infections and deaths continue to occur in patients; newly diagnosed with HIV infection, in those in the early course of ART, or in those non-adherent to HIV care and ART (Jain *et al*, 2003, Kaplan *et al*, 2000, Lunberg *et al*, 2000, Michelet *et al* ,2000, Rimland *et al*, 2002, Serraino *et al*, 2003).

Antiretroviral therapy is said to reduce the frequency of malaria by improving the immune function. Researchers measuring effect of ART on malaria have suggested a direct effect with protease inhibitors but no effect on the commonly prescribed first line non-nucleoside reverse transcriptase taken by most of the HIV patients (, Parkish *et al*, 2005, Skinner *et al*, 2004).

Cryptosporidium parvum and microsporidia are the two common opportunistic parasites that cause chronic diarrhoea and wasting among HIV-infected patients with CD4 counts <100 Cells/$mm^{3.}$ Antimicrobial agents have limited efficacy in preventing or eradicating infections with cryptosporidia or microsporidia among HIV-infected patients. Although studies assessing the changes of incidence of cryptosporidiosis and microsporidiosis are lacking, diarrhoea due to microsporidia and cryptosporidia resolved spontaneously with immune restoration among HIV-infected patients who responded to ART, (Carr *et* al, 1998, Foundraine *et al*, 1998). Therefore, institution of highly active Antiretroviral Therapy after treating for the infectious causes remains a cornerstone of treatment of diarrhoea, (Moyle *et al*, 2004).

Basic care package utilization

The basic care package is comprised of an insecticide treated net, the safe water vessel and sodium hypochlorite which together form the safe water system, cotrimoxazole prophylaxis, family HIV counseling and testing(HCT) and food supplementation.In order to obtain maximum effectiveness from basic care package, it is imperative that utilization among the target population is optimal. A study which assessed the utilization levels of the basic care package among HIV infected persons attending multi TASO centres, showed that 95 percent of the persons reported to be taking their cotrimoxazole (Colindres *et al.*, 2006). That study findings

were much more than, the 60 percent that was reported by the study which assessed the feasibility and effectiveness of cotrimoxazole prophylaxis for HIV-1-infected adults in Uganda (Watera *et al.,* 2006).

Free distribution of insecticide treated bed nets can increase usage. This is supported by two studies; one that evaluated the usage of freely distributed bed nets to pregnant women in Kinshasa, which showed that it was an effective way to achieve 80 percent use (Pettifor *et al,* 2009). Another study assessed the utilization of a basic care and prevention package by HIV-infected persons in Uganda, and reported 89 percent usage attributed to peoples' belief that insecticide treated nets prevented malaria (Colindres *et al,* 2006).However mass distribution of insecticide treated nets among non- HIV positive population of the internally displaced persons in Uganda, showed a lower (56.5 percent) utilization rate (Spencer *et al,* 2004).

A survey that evaluated challenges in implementing point-of-use water quality intervention in Homa bay, Kenya among non-HIV infected populations, reported adoption rates of only 33.5 percent for sodium hypochlorite and 18.5 percent for clay pots modified for safe water storage (Makutsa *et al,* 2001). A multi -centre TASO survey which assessed the utilization of a basic care and prevention package by HIV-infected persons Uganda survey in Uganda reported fair utilization levels for the safe water vessel; 65 percent but still poor, 36 percent utilization of water guard ® (Colindres *et al.,* 2006). Nevertheless, that study did not assess the impact of the basic care package among utilizers and non-utilizers.

CHAPTER THREE:
STATEMENT OF THE PROBLEM, JUSTIFICATION AND CONCEPTUAL FRAMEWORK.

3.1 STATEMENT OF THE PROBLEM

In sub Saharan Africa, malaria, diarrhoea and HIV infections are endemic and responsible for significant morbidity and mortality (Kaplan *et al.*, 1996, Grant *et al.*, 1997, Whitworth J e*t al.*, 2000, French *et al*., 2001, Francesconi P *et al*., 2001, Brink *et al.*, 2001). The annual cost of basic care and treatment for a person with HIV/AIDS; not including the costs of antiretroviral therapies may be as much as two to three times the annual per capita gross domestic product in developing countries (UNAIDS, 2002). There is need for integration of high impact evidence based interventions that prevent many diseases into patients' care. Some of these interventions are individual and others are combination interventions that have been proven to reduce the risks of some of these morbid-conditions among persons with HIV (UNAIDS/WHO 2000, Mermin, 2005, Lule *et al*, 2005, Watera *et al.*, 2006). For example, use of the safe water vessel and sodium hypochlorite reduced diarrhoea episodes by 25 percent (IRR = 0.75, 95% confidence interval [CI] = 0.59–0.94, *P* = 0.015 Lule et al, 2005). Utilisation levels of the different components have also been established (Colindres *et al,* 2006).

Mildmay Uganda incorporated insecticide treated nets, the safe water vessels with sodium hypochlorite (water guard®), into the basic care it provides to all AIDS patients that receive care at its centre. This is in addition to cotrimoxazole prophylaxis, family HIV counselling and testing (HCT) food supplementation and antiretroviral drugs to those who are eligible. By the end of March 2007, about 3423 kits of the basic care package (one safe water vessel, two bed nets and 4 water guard bottles) had been distributed, (March 2007 monthly report).

While evidence of effectiveness and utilisation levels of these interventions has been established under research conditions elsewhere, there is limited information about the effectiveness of the basic care package on morbidity among persons with HIV in service delivery environments in Uganda, such as the Mildmay Uganda. This study sought to assess the effectiveness of the basic care package on morbidity among persons with HIV receiving care at Mildmay Uganda and measured utilization levels of the package among the same clients.

3.2 JUSTIFICATION

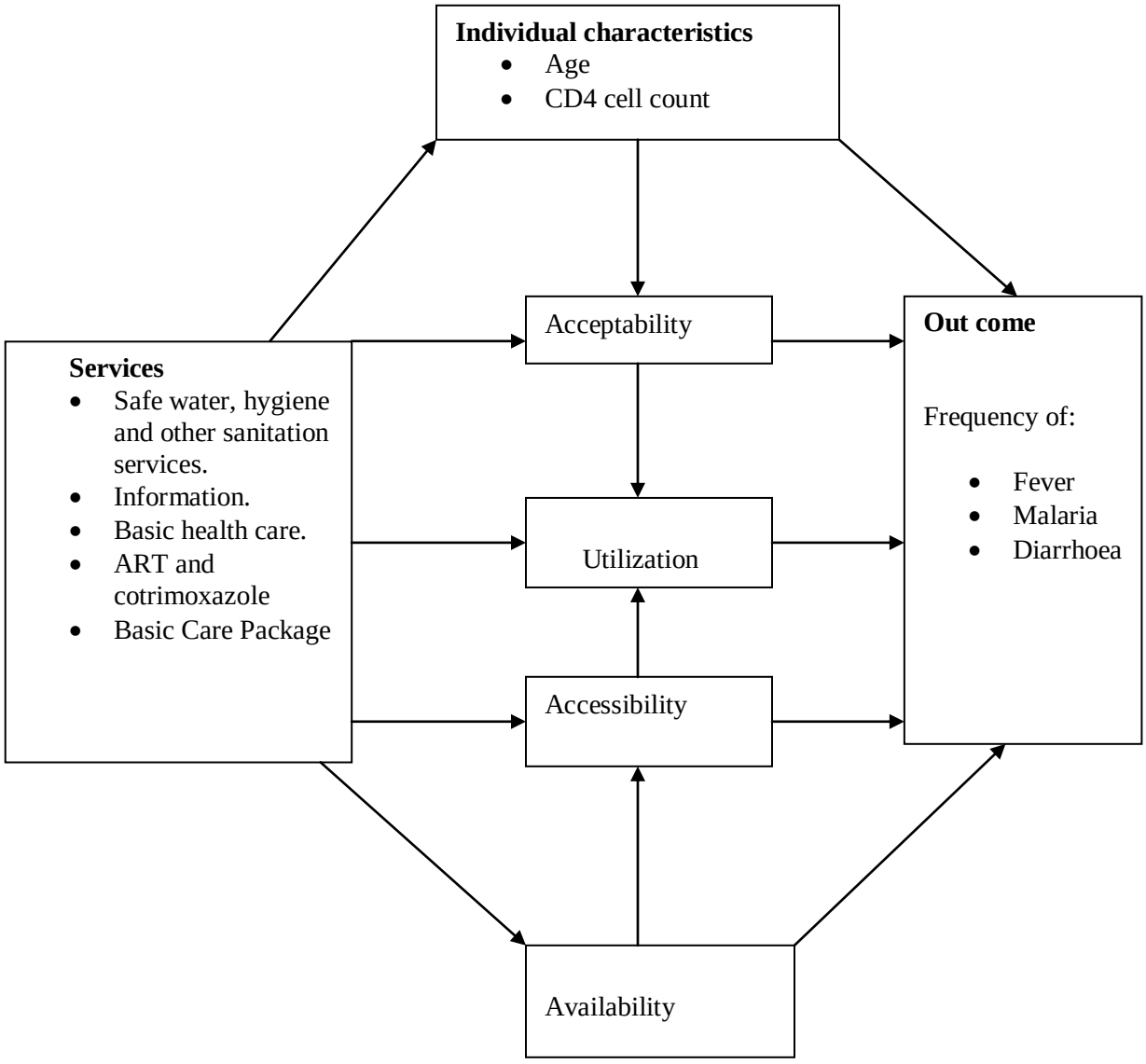
The basic care package prevented 199,553 cases of Malaria and averted 1457 deaths due to malaria and prevented 429,684 cases of diarrhoea and averted 551 deaths due to diarrhoea between January and June 2009(PACE July 2009 report). High utilization levels have been registered among persons where free distribution of different packages has occurred (Colindres *et al*, 2006, Pettifor *et al.*, 2009). Nevertheless a cross sectional study that evaluated mass distribution of insecticide treated nets programme among the internally displaced persons in Uganda, showed lower (56.5 percent) utilization levels (Spencer *et al.*, 2004).

Although the different components of the basic care package (cotrimoxazole, insecticide treated mosquito nets and the safe water system) have been proven to be efficacious in reducing morbidity and mortality among persons with HIV in Uganda (Mermin *et al* 2004, Lule *et al* 2005), there is need to evaluate their impact on morbidity in service delivery environments. In these circumstances, utilization may be lower and therefore their effectiveness may not be as high as that seen in research conditions, where follow-up and monitoring of adherence to the interventions is more regular, stricter, and rigorous.

Currently funding to HIV programmes has reduced tremendously. The distribution of the package in the first year costs $30 per person, dropping to $5 in subsequent years. Although the cost of distribution of the package is relatively cheap, the monetary value attached to this distribution, could be used for other services like food supplements, which most people perceive as important.

3.3 CONCEPTUAL FRAME WORK

3.3.1 Conceptual model



3.3.2 Narratives to the conceptual framework

A number of factors work either independently or in tandem with others to compound the burden of opportunistic infections among HIV infected individuals. As shown in conceptual framework

shown diagrammatically above, morbidity associated with malaria and diarrhoea in AIDS or HIV infected patients is influenced by a number of factors, such as individual characteristics; CD4 count, age, personal and domestic hygiene, availability, access to, acceptability and utilisation of the services.

HIV affects the immune system specifically the CD4+ cells. These cells are central to the function of both the humoral and cell mediated immunity. Thus, without helper T-cells, the body cannot make antibodies properly, nor can infected cells containing HIV (an intracellular pathogen) be properly eliminated. Consequently, the virus can: multiply, kill the helper T-cell in which it lives, infect adjacent helper T-cells, repeat the cycle, and on and on, until eventually there is a substantial loss of helper T-cells and hence the immune deficiency. To determine the immune status of an HIV person a CD4+ cell count is performed, a low CD4 count of <200cells/mm^3 in HIV infected persons is associated with increased frequency of opportunistic, other infections, and with high mortality. For example, a cohort study that evaluated malaria rates among HIV infected persons attending two rural clinics at Entebbe Uganda, showed increasing rates of malaria associated fevers among HIV infected with deteriorating immune status (French *et al*, 2001). In this Entebbe study, the rate per 1000 person years of febrile illnesses related to malaria among HIV-1infected persons with CD4 +cell count of less than 200 cells/mm^3 was 139.8(95 % CI =112-173), among persons with CD+cell count between 200 and 499 cells /mm^3, the rate per 1000person years was 93.3 (95% CI = 70-123) and among person with CD4 +cell count above 500 cell / the rate was 57.3(95 % CI =38-36)

Age in an important risk factor for malaria and malaria is more frequent in HIV infected persons than their negative counter parts .In a cohort evaluation of the effect of cotrimoxazole prophylaxis on morbidity, mortality, CD4 cell count and viral load in HIV infection conducted at TASO Tororo, malaria episodes among HIV infected children under the age of 5 were 1.7,(95% CI =1.1-2.5,p= 0.01) folds higher than in those without HIV, and they had greater parasite density as well 154 vs 61 parasites per 200 white blood cells ,p=0.03; Mermin *et al*, 2004). This is due to the naïve immune system at this age. Similar reports of increased malaria frequency have been recorded among HIV positive children (Kamya *et al*, 2007). Access and adherence to chemoprophylaxis plays a key role in reducing the occurrence of these diseases in HIV infected patients.

For centuries now, safe water and good sanitation are considered to play a vital role in reducing illness and death from infectious diseases in industrialised countries .Even when this is maintained there are some of the practices that promote infectious diseases like poor disposal of human waste, not washing hands after toilet, uncovered drinking water, and lack of hand washing materials. Diarrhoea affects 90 percent of persons living with HIV (Katabira, 1999; Monkemuller and Wilcox 2000).This was the basis for introduction of the basic care package among HIV infected patients at Mildmay Uganda.

Access to sanitary facilities and the basic care package alone is inadequate to prevent diarrhoea diseases. The impact of these facilities on incidence of diarrhoeal diseases is mediated through acceptability and utilization of available interventions. High acceptability of the available

services should ideally translate into high and appropriate utilization of available interventions. This in turn results into reduced morbidity and mortality among HIV infected patients.

Antiretroviral therapy causes immune reconstitution, which gives an individual defence to fight infections and cotrimoxazole prophylaxis has been associated with reduction in morbidity and mortality among HIV infected persons. When these services are adequate, and information about them is provided, there is increased likelihood of acceptability and utilisation, and hence reduction in morbidity.

This study focused on the effect of the basic care package on morbidity associated with fever, malaria and diarrhoea in addition to addressing questions on utilization and its impact on fever, malaria and diarrhoea related morbidity.

3.4 RESEARCH QUESTIONS

Was there an effect of the basic care package components (safe water vessel/water guard and bed nets) on fever, malaria and diarrhoea related morbidity among HIV infected persons receiving care from the Mildmay Uganda?

How did the utilization of the individual basic care package affect fever, malaria and diarrhoea morbidity among;

(i) Persons receiving care at Mildmay Uganda?

(ii) Persons that received the basic care package components?

CHAPTER FOUR:

STUDY OBJECTIVES

4.1 GENERAL OBJECTIVES

To assess the effect of the basic care package on morbidity among persons with HIV receiving care at Mildmay Uganda from 2003 to 2007 in order to justify its further distribution among HIV infected persons.

4.2 SPECIFIC OBJECTIVES

1. To measure the frequency of fever, malaria and diarrhoea related morbid events among HIV infected persons receiving care at the Mildmay Uganda, in the 12 months before and 12 months after the introduction of the basic care package

2. To compare the frequency of fever, malaria and diarrhoea related morbid events among persons who utilized with those who did not utilize the basic care package.

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CHAPTER FIVE
METHODOLOGY

5.1 Introduction

This chapter highlights the area where the study was conducted, the study population, the study design, and how subjects were selected, tools used to collect the data, variables collected and how they were defined, how quality was maintained, how data was managed, how the adequate sample size was obtained and how data was statistically analysed, the limitations and assumptions made, and ethical considerations made.

5.1 Study area

The study was conducted at Mildmay Uganda (MU). Mildmay Uganda is located 12 kilometres along Entebbe road. It is a comprehensive HIV/AIDS care facility in Kampala Uganda currently caring for over 10,000 HIV-positive, registered patients, of whom over 50% are children. Mildmay uses a family-based care model in which all members of a family are tested for HIV; those that test positive are brought into care and routinely given cotrimoxazole. Mildmay currently provides ART to over 4,982 patients; (March 2009 fact sheet) supplemented with the basic care package; cotrimoxazole prophylaxis, bed nets, safe water system. In addition, there is food supplementation especially for children and nutritional advice.

5.2 Study population

These were HIV/AIDS persons seen between January and December 2004. The assumption was that this population had at least a year of observation before they received the package, which was introduced at the end of 2004.

5.3 Study unit

Patients who had received the basic care package among the 2004 cohort.

5.4 Study design

5.4.1 Retrospective cohort study

This compared fever, malaria and diarrhoea associated morbidities in 12 months before and 12 months after the introduction of the package.

5.4.1.1 Inclusion criteria

Persons who had received the basic care kit.

Persons who had complete morbidity data for the 12 months before and 12 months after the introduction of the package.

5.4.1.2 Exclusion criteria

Those who had cough due to Tuberculosis and other chronic obstructive airway diseases.

Those who had persistent diarrhoea, which did not seem to be due to infection.

5.4.2 Cross-sectional study

This assessed the utilization levels of the different components of the package

5.4.2.1 Inclusion criteria

Persons who lived in a 35km radius from Mildmay Uganda.

Persons who consented and assented to be visited at home

5.5 Study variables

5.5.1 Dependant

5.5.1.1 Fever, malaria and diarrhoea related morbid events

These were defined in appendix one as:

- Fever as a record of a temperature of ≥37.5°C.
- Malaria as a temperature of ≥37.5°C, final the diagnosis (primary outcomes) based on reported symptoms, observed signs, and the results of laboratory investigations if any
- Diarrhoea as record of loose motions ≥3 times a day plus laboratory results if any

5.5. 2 Independent

- Socio-demographic characteristics- age, sex
- CD4+ cell counts
- Utilization of the basic care package defined as use of any; bed net, safe water vessel or sodium hypochlorite .(A person was considered to be utilizing the package if the bed net was hanging over sleeping area, safe water vessel containing water in it and bottle of sodium hypochlorite having been opened before or empty at the time of the observation ,appendix one).

5.6 Data collection

The period of the study was determined from the date, T_o , when the person received BCP. Data covering 12 months before and 12 months after, $T_{o,}$ was collected.

A list of identification numbers (Id no) of persons selected, had received the package between 2004 and 2006, therefore records reviewed were between the years 2003 and 2007.

5.6.1 Training

Two research assistants were trained for two days in data recording and approach to participants when they went on home visits.

5.6.2 Tools

5.6.2.1 Checklist`

A checklist (appendix four) was used to extract data from patient's medical records. A record of age, sex and CD4 count at the time, T_o , when persons received the package was done. On every visit, presence or absence of fever, malaria and diarrhoea, as defined in appendix one), for 12 months before and 12 months after receiving the package. If a person was on ART before and or after the package was also documented.

5.6.2.2 Observational guide

Using an observation guide (appendix two), 148 patients who consented and assented for a home visit were visited. Observations and recording whether a person had or did not have bed net, safe water vessel and water guard or not was done. In addition whether bed net was hanging oversleeping area or not, water vessel containing water in it or not and bottle of sodium hypochlorite (water guard®) having been opened before /empty or not was recorded.

5.7 Data management

The research assistants and the researcher checked the data recorded on specified forms (appendix four) for completeness, consistency and accuracy. All data were entered twice into a database using EPI Data software. The accuracy of data input was checked and validated using customized validation programmes. The cleaned data files were converted to STATA version 9 by the statistician.

5.8 Quality control

The same people were followed up for 12 months before and 12 months after the introduction of the basic care package.

Research assistants were given information about and purpose of research and were trained on how to collect data using a checklist from files and using the observational guide for collecting data about utilization of the different components of the package.

To ensure accuracy datum print outs were cross checked with original data collecting forms.

Data was edited and cleaned in Epi –info. Version 3.2.2.

Further checking was done to ensure consistency.

Analysis models were tested for the goodness of fit.

Results were compared with those of similar existing studies for validation.

5.9 Sample size calculation

5.9.1Cohort study:

$$n = \frac{2[(Z_{\alpha/2} + Z_{\beta})^2]_X \bar{P}(1-\bar{P})]}{(p_c - p_I)^2} = \frac{2[1.96+0.84)^2]*[0.53(1-0.53)]}{(0.22)^2}$$

(Jekel et al, 2001)

From each group 80

n = 160

Cotrimoxazole alone reduction in malaria episodes was 76%, ART and cotrimoxazole was 64% and that of ART, cotrimoxazole and bed nets together was 42%(Mermin *et al.*, 2006)

$Z_{\alpha/2}$ = 1.96(critical value of the standard normal distribution corresponding to

Error rate $\alpha/2$ = 5% level of significance

Z_{β} = 0.84 at power (1- β) of 80 %(critical value of the standard normal distribution

Corresponding to error β

P_c = proportion of persons who suffered morbidity before bed net introduction =64%

P_I = proportion of persons who experienced morbidity after bed net introduction =42%

$\bar{p}$ = $(P_c + P_I)/2$ = 0.64+0.42/2 = 0.53

5.9.2 Cross-sectional study:

$$n = \frac{Z^2_{\alpha/2} PQ}{\delta^2}$$ **(Thrusfield; 2005)** = $\frac{1.96^2*0.89*0.11}{0.05*0.05}$

n =150

P = utilization levels of ITN =89 %(Colindres *et al*, 2006)

Q = 100%-89%

δ =0.05

5.9.3 Sampling technique

Systematic sampling

A list of 453 identification numbers of all clients who were seen between January and December 2004 was generated from the database and 284 of these had received the package.

$n^{th} = \frac{284 \text{ (received the package among the 2004 cohort)}}{160 \text{(estimated sample)}} = 2^{nd}$

The starting point on the list was randomly selected between the 1st and 2nd number on the list. A one by second systematic sampling technique was allowed on the 284 identification numbers to obtain a sample size of 160.

5.10 Data analysis

This section highlights how each research question was answered using statistical models that have been applied in similar studies before. Missing data was handled using hot deck imputation method, where**,** a missing value was filled with a value that came from a similar record in the sample population. That means if two records were quite similar and in one record, a value for some attribute was missing a value from other similar record would be filled.

5.10.1 To assess for the effect of the package on fever, malaria and diarrhoea related morbid events before and after the package.

The mean of fever, malaria and diarrhoea related morbid events per total person visits made in 12 months before and 12 months after the introduction of the package was computed .The difference in mean of fever, malaria and diarrhoea related morbidity before and after the basic care package determined the effect of the package on morbidity and its significance was tested using a paired t-test.

5.10.2 To assess for the effect of the package on fever, malaria and diarrhea related morbid events among utilizers and non-utilizers of the package

Fever, malaria and diarrhoea related morbidity after receiving the package was considered during this analysis .Descriptive analysis was performed to explore the data. Mean episodes of fever,malaria and dairhroea related morbid events after receiving the package were performed for variables, (sex, age and CD4 cell count) and at this level, variables that had T-test or F-test p values that were <0.05 were considered for multivariate analysis.Further more frequencies and percentages of these morbid events were performed against the utilization and non utilization. In order to assess for the effect of utilization on morbidity, cross tabulations were performed between the utilization and morbidity. The effect was estimated using Chi square, and P-Values$\leq$ = 0.1 at this level were considered for multivariate analysis.

In order to determine the predictors of morbidity logistic regression was fitted. This model was selected because morbidity was binary i.e. presence or absence of fever, malaria or diarrhea related morbidity. Presence was coded one and absence coded zero. Dummy variables were created for variable, age which was used in the regression model. One of the age categories was dropped as base (reference) category while fitting the model. The interpretation of the models was based on odds ratio, and p- values of $\leq$ 0.05 were considered good predictors of the effect of the package on morbidity. The –hat and –hatsq statistics were used as the predictors to rebuild the model .The variable –hat was used to test whether the variables in the model were statistically significant predictors of morbidity and –hatsq was used to establish whether there were some relevant variables left out in the model.

5.11 Study limitations

There was a possibility of over diagnosis of malaria in this study population because a malaria diagnosis was made on the basis of a history of fever and clinical diagnosis regardless of whether the client had a laboratory diagnosis of malaria or not. Morbidity just focused on fever, malaria and diarrhoea related morbid events and not comprehensively assessing for other causes of morbidity.

It was difficult to ascertain that the persons recorded as using the basic care components at the time of the survey, had used them throughout the study period of the retrospective cohort.

Data was collected from persons who lived in both urban and semi urban areas (that is, within 35km radius of Mildmay Uganda, which could have affected the outcome since the urban population could have had bed nets before the distribution of the package, and possibly had access to safe water. Therefore the compliance to the basic care package between the two populations may have been different.

In both periods of the study that is, 12months before the package and 12 months after the package all persons were receiving cotrimoxazole because Mildmay Uganda offers cotrimoxazole routinely. It was assumed that adherence to cotrimoxazole was good. In addition, the cotrimoxazole reduces the episodes of fever, malaria and diarrhoea among clients on prophylaxis. This could have masked the actual impact of the basic care package among this study population. However, an earlier study, which assessed the effect of cotrimoxazole alone on febrile events among HIV infected persons in rural Uganda showed no change in fever febrile

events, [IRR =0.93,CI = 0.73-1.20,p=0.6] after the introduction of cotrimoxazole (Watera *et al*., 2006).

Almost all study subjects were receiving antiretroviral therapy, which could also have affected the outcome.

The morbidity analysis in this study assumed that patients attended the clinic for all morbid events. There is a possibility therefore of underestimating the episodes of fever, malaria and diarrhoea in this study population.

There was some information missing where Secondary data, was used, which led to omission of 52 files (200-148).and more still the target population was less by 12 subjects due to lack of consent/assent, which could have affected the results ,not finding them at home and failure to trace patients' homes.

During the analysis sodium hypochlorite was omitted because of its poor possession and utilization

5.12 Utilization and Dissemination of findings

Findings obtained will help in improving the basic care programme, i.e information given about use and how they use the components, at Mildmay Uganda and contribute to management of opportunistic infections in PHLA in a programmatic setting.

These findings will be presented to the Mildmay team and to the Mildmay research committee in a journal club and a report submitted to the School of Public Health as a partial fulfilment of the requirement for the award of Masters in Public Health Makerere University.

5.13 Ethical consideration

Permission to do the study was sought from the Mildmay Research committee and Makerere University School of Public health higher degree Research and Ethics review committee.

Patient's identity was kept anonymous, all documents, which could identify the participants, were kept under lock, and key to which only the study staff had access.

Consent to participate in the study was sought from eligible persons, in addition, assent from carer takers of children or the children themselves where applicable (below the age of 18 years) was obtained (Appendix three). They were reassured of confidentiality, their free choice to participate in the study, freedom to pull out of the study any time with no direct consequences to their receiving services if they refused or withdrew their consent.

FINDINGS OF THE STUDY

Introduction

This section presents findings of a comparison of fever, malaria and diarrhoea related morbidity before and after the introduction of the basic care package using retrospective cohort design. Additional data, comparing the frequency of fever, malaria or diarrhoea related morbidity among the utilizers and non utilizers of the basic care package (among the same study population as for the cohort design) is provided from a cross-sectional study. The study analysed secondary data of 148 case notes, in addition to visiting homes of the owners of these case notes with consent and assent .The reason for the unrealised 12 subjects of the target population was as a result of lack of consent and assent (5); failure to find client at home (3); and omission of some files because of a lot missing data (4). Sodium hypochlorite was omitted during the analysis because f its poor possession and utilization

Back ground characteristics

Table 6.1 Shows background characteristics of patients included in the study from 2003 to 2007. Most, 100 (67.6%) of the study subjects were females. They were aged between 1.5 to75 years, the mean age was 26.9 years (SD-15.6) and only 7(5%) were below the age of 5 years.

The biggest proportion, 39/148 (27%) of the study subjects were aged between 26-35 years and the least proportion, 6(4%) of the study population was aged 19-25 years. The CD4+ cell count at the time of receiving the basic care package was recorded for 96, (65%) of the study subjects. Most 80/96 (83%) of those with a recorded CD4 count had a count >200 cells/mm^3. (See table 6.1 below).

Table 6.1: Background characteristics of the study population (for both retrospective cohort study and survey)

Characteristics	Frequency (n)	Percentage (%)
Sex		
Female	100	67.6
Male	48	32.4
Age (years)		
<5	07	05
5-12	26	18
13-18	26	18
19-25	06	04
26-35	39	27
36-49	33	23
50+	10	07
Mean age,(SD)	26.9(15.6)	
CD4 count at baseline		
<200	16	11
200-499	49	33
500+	31	21
Not stated	52	35
Total	**148**	**100**

Retrospective study results

In order to measure the frequency of fever, malaria or diarrhoea related morbidity among HIV infected persons receiving care at Mildmay Uganda; the analysis compared the frequency of the above-mentioned diseases in the 12 months before and 12 months after the introduction of the basic care package. For bi -variate analysis a paired T-test was used to measure the significance of the difference in means of two groups and F-test for significance of the difference in means of more than two groups.

Morbidity

Fever:

Table 6.2 shows fever related morbidity 12 months and 12 months after the introduction of the basic care package

There was no statistically significant difference in mean episodes of fever related morbid events among males and males in the period before (t-test p value =0.89) and the period after the introduction of the package, (t-test, p value =0.40). (See table 6.2 below)

Notably, age had no statistically significant influence on mean episodes of fever related morbid events in the period before, (F-test, p value =4.12(0.21) and after the introduction of the package, (F-test,p value = 6.01(0.61).

There was no statistically significant relationship between baseline CD4 count and mean episodes of febrile morbid events noted in the period before (F-test ,p value =6.03(0.63) and the period after the introduction of the package ,(F-test p value = 8.11(0.43).

Table 6.2: Fever related morbidity 12 months before and 12 months after the introduction of the basic care package

Back ground characteristics	12 months before the basic care package			12 months after the basic care package		
Sex	Number of people Who suffered	Total number of fever episodes per person visits	Overall mean(SD)	Number of people who suffered	Total number of fever episodes per person visits	Overall mean (SD)
Female	19	43	0.82(1.37)	24	38	0.76(1.43)
Male	09	20	0.85(1.61	10	19	0.58(0.87)
t-test p –value		0.89			0.40	
Age (years)						
<5	01	05	1.28(1.10)	01	06	1.71(1.25)
05-12	07	15	1.46(2.30)	07	14	1.03(2.03)
13-18	08	09	0.5(0.76)	07	10	0.5(0.81)
19-25	01	03	0.83(0.98)	01	04	1.6(1.86)
26-35	08	13	0.56(1.10)	10	10	0.43(0.85)
36-49	03	13	0.70(1.15)	06	10	0.51(0.97)
50+	01	05	1.3(1.94)	02	03	0.70(1.33)
F-test (p value)		4.12(0.21)			6.01(0.06)	
CD4 counts						
<200	04	06	0.50(0.73)	05	05	0.50(0.82)
00-499	08	20	0.70(1.24)	11	17	0.55(0.96)
500+	05	18	1.54(1.85)	04	19	1.48(2.03)
Not stated	11	19	0.61(1.37)	14	16	0.44(0.87)
F-test (p value)		6.03(0.63)			8.11(0.43)	

Comparing the fever related morbidity between the period 12 months before and 12 month after the introduction of the package, there was no statistically significant reduction in the mean episodes of fever of 0.13 (p=0.3),after the introduction of the package . (See table 6.5 below)

Malaria

Table 6.3 shows malaria related morbidity 12 months and 12 months after the introduction of the basic care package

There was no statistically significant difference in the mean episodes of malaria related morbid events among male and female subjects in the period before ,(T-test ,p value = 0.77) neither was it noted after the introduction of the package,(T-test,p value =0.85).

Age had no statistically significant influence on the mean episodes of malaria related morbid events before the introduction of the package ,F-test,p value 3.5(0.32) .However, in the period after the introduction of the package ,mean episodes of malaria related morbid events significantly decreased with age, F-test,p value = 27.7(0.002) . Notably the under fives had the highest mean episodes of malaria related morbid events before and after the package,[mean(SD) = 1.28(1.1) and 0 .86(0.38)] respectively.

CD4 cell count had no statistically significant influence noted, on malaria related morbid events in the period before and after the introduction of the package, [F-test, p value = 0.78(0.60) and0.89(0.30)] respectively.

Table 6.3 Malaria related morbidity 12 months before and 12 months after the introduction of the basic care package

Back ground characteristics	12 months before the basic care package			12 moths after the introduction of the package		
Sex	Number of people who suffered	Total number of malaria episodes per person visits	Overall mean (SD)	Number of people who suffered	Total number of malaria episodes per person visits	Overall mean (SD)
Female	24	24	0.82(1.37)	19	19	0.38(0.49)
Male	10	20	0.89(1.69)	09	18	0.39(0.49)
t-test p –value		0.77			0.85	
Age (years)						
<5	01	05	1.28(1.1)	01	06	0.86(0.38)
05-12	07	15	1.53(2.38)	02	14	0.53(0.51)
13-18	08	09	0.5(0.76)	06	10	0.38(0.50)
19-25	01	03	0.83(0.98)	01	04	0.67(0.52)
26-35	08	13	0.56(1.14)	11	10	0.26(0.44)
36-49	02	13	0.70(1.15)	06	10	0.30(0.47)
50+	01	05	1.3(1.94)	02	03	0.30(0.48)
F-test(p value)		3 .5 (0.32)			27.7(0.002)	
CD4 counts						
<200	04	06	0.50(0.73)	05	05	0.31(0.49)
200-499	08	20	0.75(1.34)	11	17	0.35(0.48)
500+	05	18	1.54(1.90)	04	19	0.61(0.49)
Not stated	11	19	0.61(1.37	14	16	0.31(0.47)
F-test ,p value		0.78(0.60)			0.89(0.30)	

Overall, in comparing malaria related morbidity between the period of 12 months before and 12 month after the introduction of the package, there was a reduction in the mean episodes of malaria of 0.14, although the difference was not statistically significant, (p=0.4), see table 6.5 below)

Diarrhoea:

Table 6.4 shows diarrhoea related morbidity 12 months before and 12 months after the introduction of the basic care package.

Like for febrile and malaria related morbid events, there was no statistically significant difference in mean episodes of diarrhoea related morbid events among males and females in the period before and after the introduction of the package, (T-test, p value = 0.62 and 0.13) respectively.

There was no statistically significant relationship noted between age and mean episodes of diarrhoea related morbid events in the period before and after the introduction of the package,[F –test, (p value) =2.47(0.52)and 3.5(0.30)] respectively.

CD4 cell count had no statistically significant influence on mean episodes of diarrhoea related morbid events in the period before and period after the introduction of the package,[F-test p value =3.6(0.70) and 6.3(0.60)] respectively.

Table 6.4: Diarrhoea related morbidity 12 months before and 12 months after the introduction of the basic care package

Back ground characteristics	12 months before the basic care package			12 months after the introduction of the package		
Sex	Number of people who suffered	Total number of diarrhoea episodes per person visits	Overall mean	Number of people who suffered	Total number of diarrhoea episodes per person visits	Overall mean
Female	15	18	0.24(0.57)	13	20	0.34(0.86)
Male	04	05	0.18(0.67)	02	07	0.14(0.36)
t-test p value		0.62			0.13	
Age (years)						
<5	02	02	0.28(0.49)	02	02	0.29(0.48)
05-12	04	05	0.27(0.60)	02	07	0.27(0.60)
13-18	04	04	0.23(0.59)	03	05	0.42(0.59)
19-25	01	02	0.33(0.52)	01	03	1.00(0.52)
26-35	04	03	0.13(0.52)	02	04	0.78(0.52)
36-49	02	06	0.27(0.76)	04	03	0.15(0.76)
50+	02	01	0.20(0.63	01	03	0.30(0.63)
F-test (p value)		2.47(0.52)			3.5(0.30)	
CD4 counts						
<200	00	00	00	01	01	0.12(0.50)
200-499	08	08	0.31(0.82)	03	12	0.47(1.06)
500+	04	08	0.32(0.60)	06	06	0.19(0.40)
Not stated	06	07	0.15(0.41)	05	08	0.19(0.52)
F -test p value		3.6 (0.7)			6.3 (0.6)	

In comparing the diarrhoea related morbidity 12 months before and 12 months after the introduction of the package ,there were more reported mean episodes of diarrhoea after the introduction of the basic care package by 0.05 (p=0.4), but, this was not statistically significant. (See table 6.5 below).

However there was a statistically significant reduction in the over all morbid events (summed up together, i.e fever, malaria and diarrhoea of 0.53(95% CI = 0.0006-1.07) after the introduction of the package. (See table 6.5 below).

Table 6.5: Comparison of fever, malaria and diarrhoea related morbidity o 12 months before and 12 months after the package

Morbid events	Number of people	Mean (SD) Before	Mean (SD) after	Difference in mean	Standard error (SE)	T-test p value	95% CI
Fever	148	0.83(1.44)	0.70(1.28)	-0.13	1.52	0.30	-0.12-0.38
Malaria	148	0.84(1.47)	0.70(1.28)	-0.14	1.60	0.40	-0.17-0.46
Diarrhea	148	0.22(0.60)	0.28(0.86)	+0.05	0.70	0.40	-0.19-0.08
All	148	1.89(3.29)	1.36(2.04)	-0.58	0.27	0.05	0.0006-1.07

Cross-sectional study results

Table 6.6 below shows possession and utilisation of different components of the package by sex, age and CD4 count.

Nearly 2/3, (95/148) of the study population had a bed net and most, 78/95(82%) of them had it hanging over the sleeping area. More females 66/100, (66%) had bed nets compared to male subjects, 29/48 (60%) but males used their bed nets more than females, 25/29(86%) and 53/66 (80%) respectively. However, there was no statistically significant difference among males and females who utilized, p= 0.19 and possessed p= 0.2 a bed net. Almost 2/3 (94/148) of study population had the safe water vessel, but only a few, 31(33%) had them filled with water.

Two thirds, 2/3(66/100) of the females had the safe water vessel compared with 3/5(29/48 of male subjects, the difference not statistically significant p= 0.2. The female subjects utilised the

safe water vessel more than their male subjects, however, the difference was not statistically significant=0.9.

The number of people who had water guard® was very low 14/148(9%).All those who had water guard had their bottles having been opened before. There was no difference in possession among female subjects and male subjects (p = 0.14).

Table 6.6 possession and utilization of different components of the package by age and sex

Component	Number of persons	Present, n	Percentage, (%)	Used, n	Percentage, (%)
Bed net					
Sex					
Female	100	66	66	53	80.3
Male	48	29	60.4	25	86.2
Total	148	95	64.2	78	82.1
P value		0.20			0.19
Water vessel					
Sex					
Female	100	68	68	24	35.2
Male	48	27	56	7	12.5
Total	148	95	64.2	31	33
P value		0.51			0.90
Water guard®					
Sex					
Female	100	7	7	7	7
Male	48	7	15	7	15
Total	148	14	9	14	9
P value		0.14			0.14

Table 6.7 shows comparison of fever, malaria and diarrhoea related morbidities among utilizers and non utilizers of the different components of the package.

Sodium hypochlorite was omitted during the analysis because of its poor utilization.

At bi- variate level, bed utilization showed statistically significant reductions in morbidity related to fever and malaria ,[*Pearson chi,*χ , p value = 14.96,0.001 and 18.78,0.0009] respectively. However use of the safe water vessel showed no statistically significant reduction in diarrhoea related morbidity, [*Pearson chi,*χ , p value =1.41,0.23], neither was there a statistically significant reduction in summation of all the morbid events related to fever, malaria and diarrhoea among the utilizers of both bed nets and the safe water vessel.

At multi variate level ,adjusting for age ,there was a 58 percent reduction in fever related morbid events although this was not statistically significant ,[OR =0.42,95% CI =0.81-2.85] among bed net utilizers.The odds of reporting malaria related morbidity almost doubled [OR =1.73 ,95% CI =0.51-5.90] among bed net non -utilizers ,this was not statistically significant. Diarrhoea related morbidities were almost the same among safe water vessel utilizers and non utilizers. [OR =1.38,95% CI =0.51-5.90].

Table 6.7: comparison of fever, malaria and diarrhoea related morbidities among utilizers and non utilizers of the basic care package

Morbid events	**Basic care package** Use		**Chi, X (P value)**	**OR**	**SE**	**95%CI**	**P Value**	**ADJ OR**	**S.E**	**95%CI**	**P** value
					Net Used						
Fever	Yes	No									
Yes	16	18	15.0(0.001)	1.96	0.40	1.31-2.93	0.10	1.52	0.42	0.81-2.85	**0.19**
No	62	36									
					Net used						
Malaria	Yes	No									
Yes	28	76	18.8(0.001)	3.68	1.31	1.83-7.41	0.001	1.73	0.58	0.51-5.90	**0.32**
No	50	32									
					Vessel used						
Diarrhoea	Yes	No									
Yes	09	32	1.14(0.23)	1.79	0.86	0.70-4.60	0.59	1.38	0.32	0.51-3.82	**0.53**
No	32	99									

CI confidence interval, OR = Odds Ratio, ADJ OR= adjusted Odds Ratio, SE standard error

CHAPTER SEVEN
DISCUSSION

7.1 Summary of findings

This chapter discusses the major findings and the limitations of the study. It compares these findings to findings of other similar studies.

Most of the studies that have been conducted about the basic care package have assessed individual components of the package (Lule *et al,* 2005, Macy and Quick, 1998, Mermin *et al*,2006; Semenza *et al,* 1998; CDC, 2001;Sobsey, 2002; Sobsey *et al,* 2003 ,Watera *et al,* 2006),and not the package as a whole like this study.

The first major finding of this study was that there was no statistically significant difference in fever, malaria and diarrhoea related morbidities between the period of 12 months before and 12 months after the introduction of the package.

Many of the study subjects had put bed nets to use although the safe water system was poorly utilized.

Utilization of bed nets significantly reduced fever and malaria related morbidities but the vessel made no impact on diarrhea related morbidities

7.2: morbidity

Fever

The first major finding of this study was that there was no statistically significant difference in fever, related morbidity between the period of 12 months before and 12 months after the introduction of the package ,although a significant reduction was seen among bed net utilizers,[*Pearson chi,*χ , p value = 14.96,0.001]. Most fevers among AIDS patients are a result of infectious diseases. A survey that assessed common causes of fever requiring hospitalization in

patients with HIV/AIDS in western Kenya showed that 68 percent of fevers in children and 88 percent in adults was associated with cough and 50 percent of those who had organisms in their blood, had malaria parasites (Diero *et al,* 2004). Diarrhoea contributed 46 percent of febrile events in a survey that assessed causes of HIV-related fever in developing countries (Musangela *et a l,* 1993). Therefore general measures that reduce the spread of infection may also reduce the incidence of fever. The significant reduction seen in febrile events among utilizers of bed nets suggest that the febrile events were mainly related malaria. Bed nets have been reported to reduce the incidence of malaria (Anglaret et *al.*, 1999, Hawley *et al*, 2003, Lengeler, 2004 Mermin *et al*, 2004, Mermin *et al*, 2006a, Ter Kuile 2003a, 2003b).

The lack of a significant difference in the mean episodes of fever related morbidity 12 months before and after the introduction of the basic care package among the Mildmay study subjects ,could be explained by the fact that, all the study subjects were receiving cotrimoxazole and ART throughout the study period .In addition they could have had access to safe water since they lived in urban and semi urban areas. Some of the interventions that have been scientifically proven to reduce febrile events are cotrimoxazole prophylaxis, HAART, access to safe water and bed nets. Various studies that have reported impact of various interventions on febrile events include a prospective cohort study among HIV-infected adults seen at TASO Tororo found a reduction in febrile episodes associated with malaria of 76percent [IRR =0.24,95% confidence interval (CI) = 0.15-0.38,p <0.0001) among patients who received cotrimoxazole prophylaxis alone. Those who received a combination of cotrimoxazole and antiretroviral treatment (ART) showed a reduction of 92 percent (IRR = 0.08,95% CI = 0.04-0.17, p=<0.0001) in episodes of fever associated with malaria, and a 95 percent(IRR = 0.05, 955CI= 0.03-0.08,p =<0.0001))

reduction in episodes of fever associated with malaria was observed among those who received a combination of insecticide-treated bed nets, cotrimoxazole and ART (Mermin *et al*, 2006). That study demonstrated that the effects of these three interventions were cumulative, with bed nets showing an additive effect on the reduction in febrile events associated with malaria. Other studies have been conducted in developing countries, where the Center for Disease Control and prevention (CDC) safe water-storage container together with a sodium hypochlorite solution were assessed as a combined intervention strategy (Macy and Quick, 1998; Semenza et al, 1998; CDC, 2001; Sobsey, 2002; Sobsey et al, 2003). These studies showed improvement in the microbiological quality of household drinking water stored in the CDC safe water-storage containers to undetectable counts. Expectedly, this should be accompanied by a reduction in diarrhea-associated fevers.

Malaria

The second major finding of this study was that, the introduction of the basic care package showed no significant difference in malaria related morbidity ,however a significant reduction was seen among bed net utilizers,[*Pearson chi,*χ , p value = 18.78,0.0009] . The reduction seen among utilizers of bed nets could be explained by the high utilization levels, (82 percent) noted in this study. This finding among utilizers is in line with findings of other studies that have assessed the impact of bed nets in different populations. Those studies have reported that the use of insecticide treated mosquito nets (ITNs) reduces the incidence of malaria, as well as mortality due to malaria, in HIV-infected people in Africa (Anglaret et *al.*, 1999, Hawley *et al*, 2003, Lengeler, 2004 Mermin *et al*, 2004, Mermin *et al*, 2006a, Ter Kuile 2003a, 2003b).

The effect of the basic care package on malaria related morbidity after the introduction of the among the Mildmay study subjects was not observed in this study for several reasons such as, the study population lived in urban and semi urban areas with a possibility of having been using the bed nets even before the free distribution of the package or not utilizing them during the study period, in addition, most of the persons were receiving antiretroviral and cotrimoxazole in both study periods. Several studies have shown that cotrimoxazole prophylaxis and antiretroviral drugs are associated with lower rates of malaria, (Castleton *et al*., 2001, Mermin *et al*, 2006, Watera *et al*, 2006,). Antiretroviral therapy is said to reduce the frequency of malaria by improving the immune function, malaria was 29% less frequent per 100 cell increase in CD4 cell count (IRR=0.71,CI =0.51-0.99,p=0.04; Mermin *et a*l, 2006). Protease inhibitors have been reported to have a direct effect on the malaria parasites but no effect on malaria is shown by the commonly prescribed first line non-nucleoside reverse transcriptase administered to most of the HIV patients (Parkish *et al*, 2005, Skinner *et a*l, 2004).

Diarrhoea

The third major finding of this study was that, the basic care package showed no significant difference in the mean episodes of diarrhoea after the introduction of the package, neither was their a difference seen between utilizers and non utilizers of the safe water vessel , [*Pearson chi,*χ , p value =1.41,0.23]. The study findings are contrary to findings of the a prospective cohort study among HIV infected persons attending TASO Tororo, which showed that the use of a simple, home-based safe water system consisting of a chlorine solution to disinfect water and storage in a container with a narrow mouth, lid and a spigot reduced the frequency of diarrheoa by 25 percent (IRR =0.75 95% CI =0.59-0.94, p= 0.015; Lule *et al*, 2005).

The lack of a significant difference in diarrhoea related morbidity after the introduction of the package and among utilizers of the safe water vessel among persons seen at Mildmay Uganda ,was possibly because of the low utilisation levels of the safe water vessel and water guard, that is, only 33 percent and 15 percent respectively. In addition, there is a possibility that the study population had access to safe water since they lived in urban and semi-urban areas. A systematic and a meta-analysis of water, sanitation, and hygiene interventions to reduce diarrhoea in less developed countries, showed a bigger, 39 percent (RR 0·61,95% CI =0·39–0·94) reduction of diarrhoea episodes among persons in a rural setting when compared with 14 percent (RR = 0·86 95 % CI =0·57–1·28, Fewtrell et al, 2004) that was seen among persons who lived in urban and semi urban areas. More still, all the study subjects were receiving cotrimoxazole. Cotrimoxazole has been reported to reduce diarrhoeal episodes by 67 percent [IRR = 0.33, 95% CI = 0.24-0.46, P < 0.000; Lule *et al,* 2005).

7.3 Possession and utilization.

In this study, the health facility records showed that all the study clients received the basic care package, and two thirds were found to have the package when visited at home. The lower possession levels could be as a result of the study subjects giving away the basic care package which was the reason given by 24 % of the subjects who were found not to have bed nets (Colindres *et al.,* 2006). In addition there is a possibility of these components wearing out; this study was done four years after the distribution of the package.

Utilization levels of bed nets were high (82 percent) which are comparable to findings of two studies; one that evaluated the usage of freely distributed bed nets to pregnant women in Kinshasa,which reported that 80 percent of these women reported sleeping under bed net the night before the interview when they had received free bed nets when compared with the 25 percent reported before the free distribution of bed nets(Pettifor *et al,* 2009). Another study which assessed the utilization of a basic care and prevention package by HIV-infected persons in Uganda, reported 89 percent utilization rate (Colindres *et al,*2006).

The low utilization levels of the safe water vessel of 33 percent and water guard® of 14 percent noted in this study are contrary to findings of a similar study conducted in different TASO facilities which reported a bigger proportion (74 percent), observed using the safe water vessel 34 percent confirmed treating their drinking water with water guard® by finding detectable chlorine residuals in their drinking. However, a survey that evaluated challenges in implementing a point-of-use water quality intervention in Homa bay, Kenya among non – HIV infected populations reported lower adoption rates of only 33.5 percent for sodium hypochlorite and 18.5 percent for clay pots modified for safe water storage (Makutsa *et al* ,2001). The difference in the two sets of results could be explained by the fact that the TASO study was conducted shortly (three to seven months) after the study subjects received the basic care package. This way, the TASO subjects expectedly had all the components of the package compared to the Mildmay study, which was conducted in over a year of receipt of the package by most individuals.

7.4 Limitations of the study

In interpreting the findings of this study, the following limitations have been put into consideration. Firstly, there was a possibility of over diagnosis of malaria in this study population, malaria diagnosis was made on the basis of a history of fever and clinical symptoms and signs of malaria ,regardless of whether the client had a laboratory diagnosis of malaria or not.

Secondly, it was difficult to ascertain that the persons recorded as using the basic care components at the time of the survey, had used them throughout the study period of the retrospective cohort.

Thirdly, data was collected from persons who lived in both urban and semi urban areas (that is, within 35km radius of Mildmay Uganda, which could have affected the outcome since the urban population could have had bed nets before the distribution of the package, and possibly had access to safe water. Therefore the compliance to the basic care package between the two populations may have been different.

Fourthly, in both periods of the study that is, 12months before the package and 12 months after the package all persons were receiving cotrimoxazole and ART. Mildmay Uganda routinely offers cotrimoxazole to its clients. These two interventions have been proven to be effective against malaria and diarrhoea diseases (Mermin *et al,* 2004; Mermin *et al,* 2006).

Lastly, the calculated sample size was less by 12 subjects due to lack of consent and assent, a lot of missing data in the case notes and failure to find client at home.

Analysis on sodium hypochlorite was not done because of its very low possession and utilization.

Morbidity assessment was limited only to fever, malaria and diarrhoeal related morbidity events.

CHAPTER EIGHT
CONCLUSION AND RECOMMENDATIONS

8.1 CONCLUSION

Recognising the limitations mentioned above, the basic care package showed no significant difference in fever, malaria and diarrhoea related morbidities among AIDS patients attending Mildmay Uganda. Its worth noting that not many studies have assessed the effect of the package as whole.

Many of the study subjects had put bed nets to use unlike the safe water system.

Bed utilization reduces malaria related morbidity as earlier studies had reported (Mermin *et al,* 2006)

8.2 RECOMMENDATIONS

The lack of a significant effect of the basic care package on morbidity in this study could have been as result of study being conducted on urban and semi urban population. In addition this population was exposed to anti retroviral therapy. A prospective study conducted among HIV persons living in rural settings or a retrospective study among HIV infected persons who received the basic care package and remained ART naïve for a long time, like, HIV infected persons seen at TASO facilities, would be better studies for addressing the study question.

It is important to understand why only one third of individuals were using the safe water vessel.Therefore,an in depth survey to establish factors associated with the use of the package

needs to be conducted and come up with strategies of promoting its use since its effectiveness has been established by other studies.

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APPENDICES

Appendix one: Definition of variables

Variable	Definition
CD4 count	CD4 record that was within 3 months before and after the date of receiving the package was considered the baseline CD4.
Being on ART	A person was recorded to be on ART in that period (before or after), if they had received ART for $\geq$ 3 months of the 12 months.
Fever and or malaria	Every recorded fever with a temperature of $\geq 37.5^{\circ}$C and the diagnosis (primary outcomes) based on reported symptoms, observed signs, and the results of laboratory investigations if any was considered to be malaria or fever.
Diarrhea	For every record of reported diarrhoea (loose motions $\geq$3 times a day), and the final diagnosis plus laboratory results if any within the period of the study was considered as diarrhoea.
Bed net utilization	Bed net hanging over sleeping area
Safe water vessel utilisation	Vessel containing water
Water guard® utilisation	Bottle having been opened

Appendix two: Questionnaire

ID no…… Age…… Sex…F/M ……

Address.....… ART status: Y/N……

Date of package……

No of household members .....…adults……..children……

OBSERVATIONS TO BE MADE BY THE RESEARCH ASSISTANT *(Observe/Look at and circle the correct choice/choices – do not read the options.)*

1.What type of water storage vessel does the household use for storing drinking water?

(1) Wide mouthed (a cup can fit through the opening)

(2) Narrow mouthed (a cup cannot fit through the opening)

(3) Other (Describe) _____

2. Is the water in the storage vessel covered?

(1) Yes *(2) No*

3. Does the patient have water guard bottle? Y/N

4 Has it been opened? Y/N

5. Does the client have a net?……..Y/N?

6. is the net hanging at the sleeping space? .....Y/N

Appendix three: Consent /assent form

Mildmay Uganda

Consent to Participate in a Research Study

BASIC CARE PACKAGE UTILISATION BY MILDMAY CLIENTS

You are being asked to participate in a research study. The purpose of this document is to provide you with information to consider in deciding whether to participate in this research study. Your consent should be made based on your understanding of the information given about the study. Please ask questions, if there is anything you do not understand. Your participation is voluntary and will have no effect on the quality of your medical care if you choose not to participate

1. INVESTIGATOR (S) CONDUCTING THE STUDY

PRINCIPAL INVESTIGATOR (PI): Dr.Faith Nakiyimba

Medical officer

Mildmay Uganda

P.O BOX 24985 k'la

077-2193978

CO- INVESTIGATORS (CO-PI): trained interviewers

Mildmay Uganda

2. SOURCE OF SUPPORT

There is no outside funding.

3.SITES OF THE RESEARCH STUDY

The Mildmay Uganda

4. PURPOSE OF THE RESEARCH STUDY

The purpose of the research is to assess the basic care effect on morbidity among HIV patients.

5. ELIGIBILITY

You are being asked to participate because you or your child received the basic care package

6. PROCEDURES

A home visit may be done to you to observe if and how you or your child are using one or more components of the package.

7. RISKS

No one will know any thing about t your home, because information will be written against a number but not your name and kept confidential

.

8. BENEFITS

This is a study that wants to assess the effect of the package on your health, which will help in designing interventions that will make your life better.

9. CONFIDENTIALITY

Information related to you will be treated in strict confidence to the extent provided by law. Your identity will be coded and will not be associated with any published results. Your code number and identity will be kept in a locked file of the Principal Investigator.

By signing this form, you are giving consent for any future studies about the basic care package. The information will remain the property of Mildmay records and may be shared with

other researchers as long as confidentiality is maintained. You will not receive results of any of the findings .

Results of studies may be reported in medical journals or at meetings. However, individuals in the study will not be identified in any way.

10. FREEDOM TO WITHDRAW

Your participation in this study is voluntary and you may stop your participation at any time without prejudice and without affecting future health care

VOLUNTARY CONSENT

All of the above has been explained to me and all of my current questions have been answered. I am encouraged to ask questions about any aspects of this research study. If I have questions in the future, I should contact:

Name: _Dr Faith Nakiyimba Title: medical officer Phone Number: 0772193978

Any questions I have about my rights as a research participant will be answered by the staff at the Mildmay center, If you decide to take part in this research study, you will be visited at home to observe how you use the package.

By signing this form I do not waive any of my legal rights.

By signing this form, I agree to participate in this research study.

(Print) Name of Participant	Signature of Participant	Date
(Print) legal Representative	Signature of Health Legal Representative	Date

I certify that the nature and purpose, the potential benefits and possible risks associated with participation in this research study have been explained to the above individual and that any questions about this information have been answered. A signed copy of this consent will be given to the participant.

(Print) Name of Person Obtaining Consent/ PI designee	Signature of Person Obtaining Consent/ PI designee	Date

I certify that the individuals named above as "participant" and "person obtaining consent signed this document in my presence.

(Print) Name of Witness	Signature of Witness	Date

I certify that the "Person Obtaining Consent" is an authorized "Designee."

(Print) Name of Principal Investigator	Signature of Principal Investigator	Date

ASSENT

All of the above has been explained to me and all of my current questions have been answered. I am encouraged to ask questions about any aspects of this research study. If I have questions in the future, I should contact:

Name: _Dr Faith Nakiyimba Title: medical officer Phone Number: 0772193978

I want to take part in this study. I know I can change my mind at any time.

_____ Verbal assent given Yes □
Print name of child/guardian

Written assent if the child chooses to sign the assent.

_____ _____ _____
Signature of Child/guardian Age Date

I confirm that I have explained the study to the participant to the extent compatible with the participants understanding, and that the participant has agreed to be in the study.

_____ _____ _____
Printed name of Person obtaining assent | Signature of Person obtaining assent | Date

Appendix four: Data collecting sheet

Id no……. Age…… sex……

Date when BCP was received……

Number of household members…… ART status…….

Baseline CD4…… baseline weight……

Disease occurrence	Clients id no	Number of visits before associated with		Number of visits after associated with		labs
		Fever Malaria diarrhoea	No Fever Malaria diarrhoea	Fever Malaria Diarrhoea	No Fever Malaria diarrhoea	
Fever						
Malaria						
Diarrhoea						