*IOSR Journal of Pharmacy and Biological Sciences (IOSR-JPBS)*
*e-ISSN:2278-3008, p-ISSN:2319-7676. Volume 13, Issue 1 Ver. VI (Jan. – Feb. 2018), PP 27-35*
*www.iosrjournals.org*

# Efficacy and Safety of Herbal Formulations Used For Management of Hiv/Aids In Mombasa County

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***Abstract:***
***Background:*** *Traditional medicines are not understood globally and hence are not fully exploited. Pwani herbs clinic in Mombasa dispenses herbal medicines to manage HIV and AIDS. There was need to subject these herbs to formal clinical research to ascertain their efficacy and safety.*
***Objectives:*** *To isolate the components of the herbal formulations Antiretroviral herbal formulation (VIRAD) and immune boosting herbal formulation (IMB) and determine their efficacy and safety.*
***Design:*** *A longitudinal study for People Living with HIV/AIDS (PLWHA) attending Pwani herbsclinic and measure physiological, immunological and Viral Load parameters. Period of study was one year; patients were screened at every two months. Every sample was its own control from baseline.*
***Settings****: Pwani herbs Clinic Mombasa and Laboratory analysis done at Bomu Medical clinic in Mombasa.*
***Study participants:*** *Adult male and female patients confirmed HIV positivethat use herbal treatments for management of HIV/AIDS disease/status.*
***Results:*** *Phytochemical components (mg/100g);* ***Virad****; Phenols 84.4mg, Saponins 531mg, Tannins 324mg, Alkaloids 2304mg, Flavonoids 2173mg, Protein 442mg and Lipids 2444.2mg. Trace elements µg/g) K 12922±103Na 475±4 Ca8861±71 Mg547±1 Fe361±4 Cu 98.6±1.5 Zn43.7±0.9.****IMB****; Phenols 75.1mg, Saponins564mg, Tannins 51mg, Alkaloids 1531mg, Flavonoids 2533mg, Proteins 544mg, Lipids 2553.8mg.Trace elements (µg/g) K 12085±87 Na 598±11 Ca 6047±46 Mg 545±1 Fe348±4 Cu 5.9±0.4 Zn25.3±0.6.At months 2, 4, 6, 8 and month 10, 23/188 discontinued. Out of these 3 died while 20 developed other complications such as tuberculosis and cancers were discontinued from study.At completion of study weight gained by average 17kg, BMI increase 4.85, CD4 raise 126, CD8 declined 15, CD4/CD8 raise 0.19, Viral load drop 864, Hemoglobin Hb raise 3g/dl, RBC raise 1.3, WBC raise 1.6, ESR drop 21. Toxicity on kidney Urea drop 0.1g/dl, Liver GGT, AST, ALT drop0.3g/dl. Virad and IMB; Flavonoids, Alkaloids and lipids were of highest concentrations in these formulations have antioxidant molecules that positively affect physiological and immunological factors, boost immunity, raise CD4 count and raise CD4/CD8 ration and decrease viral load. Not harmful on Endocrine organs Liver & kidney. Virad and IMB have virastatic effects and could be considered for development and subsequent inclusion in management of HIV/AIDS. Conclusions: Virad and IMB were effective and safe with virastatic potentials to use on people living with HIV/AIDS. More study is needed for long term treatments.*

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Date of Submission: 15-02-2018 Date of acceptance: 03-02-2018

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## I. Introduction

The human immunodeficiency virus (HIV) infection has been a pandemic for more than three decades and has always been concentrated in the developing world especially, Sub-Saharan Africa. Acquired Immunodeficiency Syndrome (AIDS) that is sequelae of advanced HIV infection, stands as the greatest threat to economic, social and human development in many countries. Many people with AIDS have no access to medication to relieve their pain and suffering. About 25 million adults and children have already lost their lives to the disease globally, with two thirds of these deaths being from Sub-Sahara Africa (UNAIDS, 2005).The management of HIV and AIDS has enormous challenges coupled with the ad-verse effects presented by the antiretroviral medicines currently in use in the country (WHO, 2005). Highly active antiretroviral therapies (HAART) are supposed to improve overall health status of People Living with HIV and AIDS (PLWHA) (WHO, 2005). However, the side effects resulting from the antiretroviral drugs (ARVs) occasionally lead to poor adherence to the drug regimens (WHO, 2005). Some of the side effects of common ARVS used in Kenya include: loss of appetite, nausea/vomiting, diarrhea, loss of taste, anemia and constipation (Heath et al.,2002).

The common and prominent signs of fat redistribution syndromes include facial and limb wasting, central and /or localized adiposity and visceral fat accumulation. These side effects include lipodystrophy, dyslipidaemia, insulin resistance, an increase in cardiovascular risks and birth defects. This is common in individuals taking nucleoside reverse transcriptase inhibitors (NRTIs) and protease inhibitors (PIs) (Heath et al.,2002). Modern herbal remedies are usually found as a whole or semi purified extracts and ideally should be standardized for their active constituents to ensure clinical reproducibility (WTMS, 2005). The use of herbal medicines in the coastal areas of Kenya has risen as many practitioners use the available media to advocate for their use. Pwani herbs clinic in Mombasa is a popular clinic that dispenses anti-retroviral herbal formulation (Virad) and immune booster (IMB) to manage HIV and packaged in 500mg capsules and dispensed as alternative to the conventional ARVs. Virad is an herbal combination of multiple active constituents believed to combat viral infections. IMB is also an herbal combination of multiple active constituents believed to boost immune system. The aim of this study was to isolate their compositions, ascertain their efficacy and safety.

## II. Materials and Methods

Study setting: The center for microbiology research KEMRI- Kwale and Pwani herbs clinic Mombasa, and Bomu medical hospital Mombasa, KenyaStudy Design: This study adopted the statistical procedure by Whitaker et al. (2006). The self-controlled case series (SCCS) method was an alternative study method for investigating the association between a transient exposure and an adverse event. A longitudinal study for People Living with HIV/AIDS (PLWHA) attending clinic at Pwani herbs, where physiological and immunological parameters, CD4/CD8 and Viral Load were measured and Toxicity values assessed. Period of study was one year; patients were screened at every two months. Every sample was its own control from baseline.Cases: Adult male and female patients confirmed HIV positive living with HIV/AIDS in Mombasa, which used herbal treatments for management of HIV/AIDS disease/status, aged 18 years and above, that, gave Informed Consent.Procedure for data collection:This was a purposive random sampling method, where Male and Female Patients were recruited as they attend the clinic for treatment. Laboratory analysis was done at Bomu Medical clinic laboratories in Mombasa. Patients were registered in individual files with study numbers allocated to each. Recruited Patients were weighed and their heights were measured at the clinic. The Body Mass Index (BMI) was then computed for each patient.Ethical Approval: Approval was obtained from the secretariat of KEMRI/ National Ethics Review Committee, Reference KEMRI/RES/7/3/1. Informed Consent from patients who were willing to participate was obtained. They were required to read the consent form and sign after understanding its contents.Anthropometric assessments: was carried out through weight, height, mid upper arm circumference and changes in body mass were recorded. The BMI obtained from weight in kilograms divided by square of the height in meters. This test was also to evaluate physiological parameters and to provide status for nutritional and impact of illness.Blood Collection: Venous blood sample was collected from each study patientusing a 10ml syringe and dispensed into two tubes of 2ml whole blood in purple top vacutainers, labeled appropriately, packaged and transported to Bomu Medical clinic laboratories for analysis.Hematological assessments: Analysis for WBC and RBC was done on full blood count by coulter; 2ml of whole blood in purple top vacutainers were used. Total WBC and differential counts, hemoglobin (Hb) and RBC to assess the complete blood count were done. Erythrocyte sedimentation Rate (ESR) was done in tube test to assess sedimentation of erythrocytes per hour using standard methods.Immunological assessments: CD4/CD8 T-cell Assessment, 2ml Blood samples were collected for CD4/CD8 in vacutainer tubes and Flow Cytometry was used to determine percentages and absolute numbers of CD4 and CD8 T Lymphocytes, For the enumeration of T-Cells, (Wallace, 2003).Viral load Assessments: The Roche Amplicor HIV-1 Monitor Test Molecular method uses Polymerase Chain Reaction (PCR) to monitor viral load according to procedure by (Christine Johnson, 2001).Organ Functioning Tests: Liver function tests (LFTs or LFs), Total protein, albumin, bilirubin, alkaline phosphate and alanine aminotransferase (ALT) / aspartate aminotransferase (AST) were done using calorimetric methods and autoanalyser.Kidney Function Tests: Blood Urea Nitrogen (BUN) test is often done to check kidney function. Blood samples were obtained through Venipuncture. A test was done to measure the amount of urea nitrogen in the blood (Logan Mclennan, 2010) Phytochemical analysis: The plant materials for the study formulations were provided by Pwani Herbs Laboratories from Kilifi County. They were dried under a sun drier until dry and ground into powder with by a grinder then stored in air tight bags.Laboratory scale extraction: The raw materials were placed in a thimble made of filter paper and inserted into the wide central tube of the extractor. Solvent was placed in the flask and brought to its boiling point. Its vapors passed up the larger right hand tube into the upper part of the drug and then to the condenser where it condensed and dropped back on to the drug. During its percolation, the soluble constituents were extracted.Hot extraction (Quality control methods, 1998): 4.0 grams of coarsely powdered air-dried material, was placed in a glass-stoppered conical flask. 100 ml of water were added and weighed to obtain the total weight including the flask, was well shaken and left to stand for 1 hour. A reflux condenser was attached to the flask and boiled gently for 1 hour; cooled and weighed. About 25 ml of the filtrate were transferred to a tarred flat-bottomed dish and evaporated to dryness at 105 °C for 6 hours and

cooled in a desiccator for 30 minutes, and was weighed. The content of extractable matter was calculated in mg per g of air-dried material. Gas chromatography–mass spectrometry GC-MS: GC analysis separates all of the components in a sample and provides a representative spectral output. The sample was injected into the injection port of the GC device. The GC instrument vaporized the sample, separated and analyzed the various components. Each component produced a specific spectral peak that was recorded on a paper chart(Frederic Douglas, 2015).Phytochemical screening: Tannins: To 2 ml of aqueous extract 2 ml of 5% $FeCl_3$ was added. Formation of yellow brown precipitate indicates the presence of tannins (Jigna et al., 2007). Alkaloids: The 1 gram powdered drug was extracted for 15 min with 10ml methanol on water bath. The mixture was filtered and the filtrate was evaporated to 2ml of filtrate. To 2 ml methanolic filtrate, 1.5 ml of 1% HCl was added. After heating the solution in water bath, 6 drops of Mayors reagents/Wagner's reagent/ Dragendroff reagent was added. Formation of orange precipitate indicates the presence of alkaloids (Oguyemi, 1979).Saponins: 2 grams powdered drug was extracted for 15 min in aqueous solution and subjected to frothing test. Frothing persistence indicated presence of saponins. Latter the froth was mixed with few drops of olive oil. Formation of emulsion indicates the presence of saponins (Sofowora, 1993). Cardiac glycosides: The 1 gram powdered drug was extracted for 15 min with 10ml methanol on water bath. The mixture was filtered and the filtrate was evaporated to 2ml of filtrate. To 2 ml methanolic filtrate, 1 ml of glacial acetic acid and 1-2 drops of $FeCl_3$ were added followed by 1 ml of concentrated $H_2SO_4$. Appearance of brown ring at the interface indicates the presence of cardiac glycosides. A violet ring may also appear below the brown ring (Trease and Evans, 1989).Terpenes: To 2 ml of aqueous extract, was added 5 ml of chloroform, 2 ml of acetic anhydride and 2 ml of concentrated $H_2SO_4$ to form a layer. The formation of a reddish brown coloration at the interface indicates the presence of terpenes (Harborne, 1973).Flavonoids: 2 grams plant material was extracted in 10 ml ethanol or water. To 2 ml filtrate few drops of concentrated HCl followed by 0.5 g of zinc or magnesium turnings was added. The formation of magenta red or pink colors after 3 minutes indicated the presence of flavonoids (Jigna et al., 2007).Phenolics: To 2 ml of ethanol or aqueous extract, 1 ml of 1% ferric chloride solution was added. The formation of a blue or green color indicates the presence of phenols (Martinez, 2003).Mineral Composition: Atomic Absorption Spectrophotometry (AAS) Model: 210VGP (Scientific equipment) was used to determine the quantity of magnesium, chromium and vanadium in the plant extracts (Hagen Stos-nach, 2005). This was used for the determination of the concentration of specific heavy metals. Atoms in the ground state absorb light of a specific wavelength, characteristic of the particular atom, when the light passes through an atomic vapor layer of the element to be determined. An automated continuous-flow hydride vapor generation system was used for arsenic and mercury.Total Reflection X-Ray Fluorescence (TXRF) system was used to determine the content of Manganese, Iron, Nickel, Copper, Zinc, Arsenic, Lead, Potassium, Titanium, Vanadium, Bromine, and Calcium in the herbal samples Virad and IMB. The spectral data for analysis were collected using personal computer based Canberra S-100 multi-channel Analyzer (MCA). The acquisition time applied in the TXRF measurement was 1000 seconds. For data analysis, the X-ray spectrum analysis and quantification was done using IAEA QXAS software (QXAS, 1992) that is based on the fundamental parameters method (FPM). The composition of Virad and IMB sample was extrapolated by its fluorescence X-ray intensity of each element. The results were ex-pressed in parts per million (ppm) (Hagen Stos-nach, 2005).Statistical Analysis: The statistical analysis tool used was R version 3.0.2 software. Analysis proceeded as follows; first, average and individual level changes for phenotypic, immunological and hematological and biochemical parameters were explored using trend graphs. Second, each of these parameters was analyzed further using linear mixed effects model. The random intercepts and random slopes were tested using a mixture of chi squares since the null variance hypotheses lied in the boundaryas each individual had a different evolution pattern, while fixed effects included time, gender and age. Suitable mean structures for each of the outcomes were explored using polynomials and covariance structure was used for all the variables.

## III. Result

Participants at baseline:A total of 188 patients were recruited into this study. During the follow up 21 out of 188 patients dropped out of the study; 3 died while 18 developed other complications such as tuberculosis and cancer. They were referred for specialized treatment at other conventional hospitals.

**HIV/AIDS participants by Age and gender**

The numbers in brackets n % number of patients over the total 188 participants.

| Gender | | Age of HIV/AIDS patients | | | | Total |
|---|---|---|---|---|---|---|
| | <18 | 19 – 30 | 31 – 40 | 41- 50 | >50 | <18 to >50 |
| F (%) | 4 (2.1) | 33(17.6) | 55(29.3) | 24(12.8) | 8 (4.2) | 124(66) |
| M (%) | 1 (0.5) | 4 (2.2) | 28(14.9) | 27(14.4) | 4 (2.1) | 64 (34) |
| Total | 5 (2.6) | 37(19.7) | 83(44.1) | 51(27.1) | 12(6.4) | 188(100) |

**HIV/AIDS participants by CD4 staging and gender**

The numbers in brackets are % expressions over the total participants 188.

| Sex | | Age of HIV/AIDS patients | | | | Total | p-value | | |
|---|---|---|---|---|---|---|---|---|---|
| | <18 | 19 – 30 | 31 – 40 | 41- 50 | >50 | <18 to >50 | $\chi^2$ | df | p |
| F (%) | 4 (2.1) | 33(17.6) | 55(29.3) | 24(12.8) | 8 (4.2) | 124(66) | 105.1 | 5 | 0.001 |
| M (%) | 1 (0.5) | 4 (2.2) | 28(14.9) | 27(14.4) | 4 (2.1) | 64 (34) | | | |
| Total | 5 (2.6) | 37(19.7) | 83(44.1) | 51(27.1) | 12(6.4) | 188(100) | | | |

The numbers in brackets n % number of patients over the total 188 participants

**Phytochemical composition of Virad and IMB.**

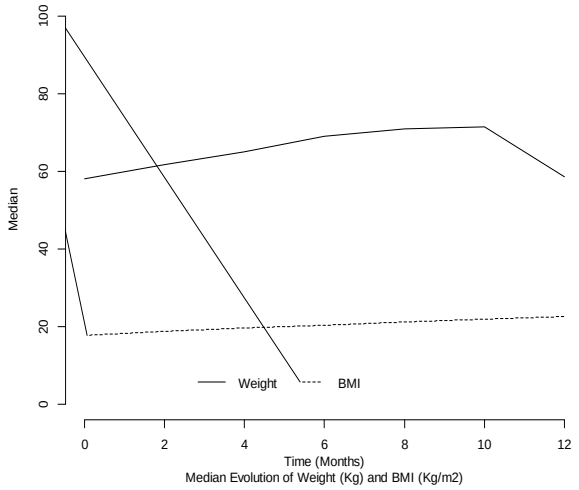
| Drugs | Phenols | Saponins | Tannins | Alkaloids | Flavonoids | Cardiac glycosides |
|---|---|---|---|---|---|---|
| | Proteins | Lipids | | | | |
| Virad | 0.08± 0.02 | 0.53± 0.00 | 0.32 ± 0.01 | 2.30 ± 0.01 | 2.17 ± 0.03 | 0 |
| | 0.44± 0.03 | 2.44± 0.02 | | | | |
| IMB | 0.08± 0.02 | 0.56± 0.00 | 0.05± 0.00 | 1.53± 0.02 | 2.53 ± 0.00 | 0 |
| | 0.54 ± 0.00 | 2.55± 0.0 | | | | |

Key: Bioactive Agents Quantity/100g of plant material (g %), Mean ± SD of triplicate determination on the basis of dry weight.

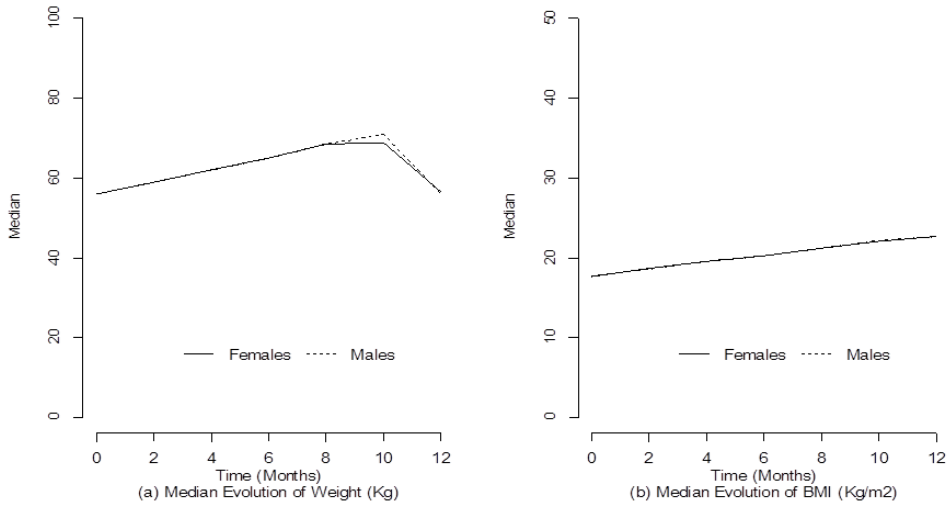
**Mineral components of VIRAD and IMB and the quantity orally administered daily to each patient.**

| Element | Mineral levels(µg/g) | | Daily mineral intake (µg) | | RDA (ug/day) |
|---|---|---|---|---|---|
| | VIRAD | IMB | VIRAD (1g/daily) | IMB (1.5g/daily) | |
| K | 12922±103 | 12085±87 | 12922±103 | 18127.5±154.5 | $2x10^6$ |
| Ca | 8861±71 | 6047±46 | 8861±71 | 9070.5±69 | $1x10^3$ |
| *Na | *475±4 | *598±11 | *475±4 | *897±6 | $5.0x10^5$ |
| Ti | 45.7±2.5 | 17.3±1.5 | 45.7±2.5 | 26.0±2.3 | 0.015 |
| *P | *71±2 | *63±2 | *71±2 | *94.5±3 | $7.0x10^5$ |
| V | 6.0±1.6 | 5.8±1.1 | 6.0±1.6 | 8.7±1.7 | 0.064 |
| *Cr | *89±23 | *57±24 | *89±23 | *85.5±36 | 0.01 |
| Mn | 120±3 | 131±2 | 120±3 | 196.5±3.0 | $2.3x10^3$ |
| *Mg | *547±1 | *545±1 | *547±1 | *817.5±1.5 | 150 |
| Fe | 361±4 | 348±4 | 361±4 | 522±6.0 | $8.0x10^3$ |
| Ni | BDL | BDL | BDL | BDL | |
| Cu | 98.6±1.5 | 5.9±0.4 | 98.6±1.5 | 8.9±0.6 | $1.5x10^3$ |
| Zn | 43.7±0.9 | 25.3±0.6 | 43.7±0.9 | 38.0±0.9 | $1.1x10^4$ |
| As | 11.2±0.4 | 1.4±0.2 | 11.2±0.4 | 2.1±0.3 | - |
| Br | 13.6±0.4 | 9.6±0.3 | 13.6±0.4 | 14.4±0.5 | 0.08 |
| Pb | 2.8±3 | 6.7±0.4 | 2.8±3 | 10.1±0.6 | - |

Key: Results are expressed as Mean ± Standard Deviation (SD) for three replicates, Dosage of VIRAD is 1000mg once daily while IMB is 500mg three times a day,*Values with asterisks as superscript were determined using the AAS while those without were determined using TRXF. BDL is below detectable levels.Changes in Weights and BMI: From baseline individuals had different weights and BMI measurements. As patients took Virad and IMB, the weight increase over time was not significant (p – value >5%).Effects of Virad and IMB on Weight and BMI: At baseline, both males and females patients were underweight. As the patients took the medications Virad and IMB, phenotypic changes were evident. Weight for both male and female increased from baseline with average median weight of 60.5 kg to 76.0 kg at end of the study.

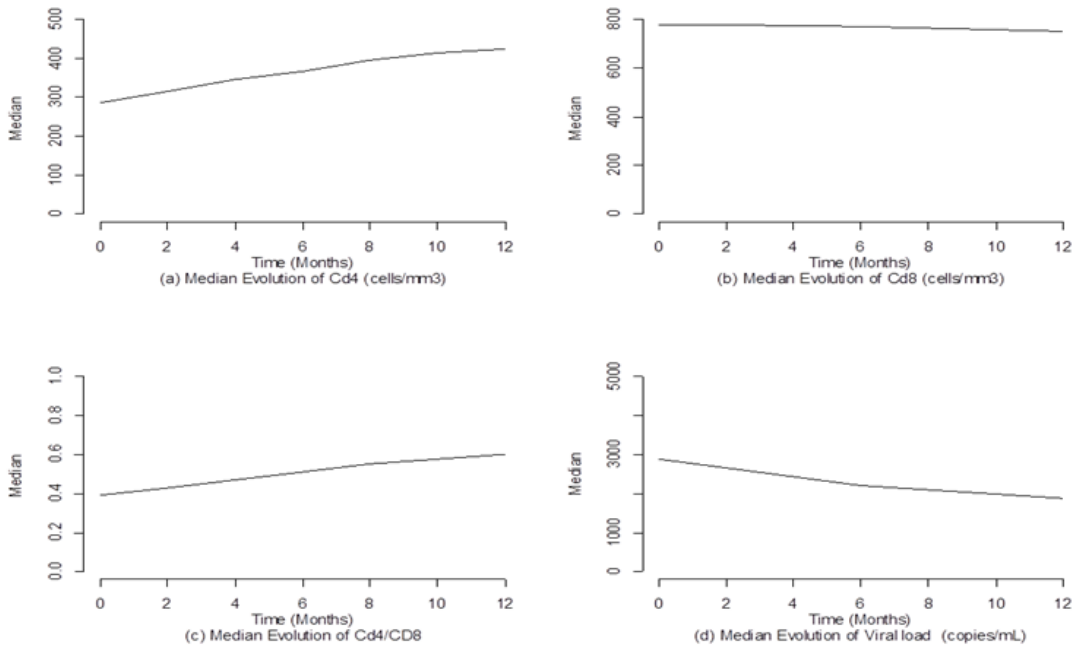



Phenotypic changes in Average Weight & Average BMI Parameters

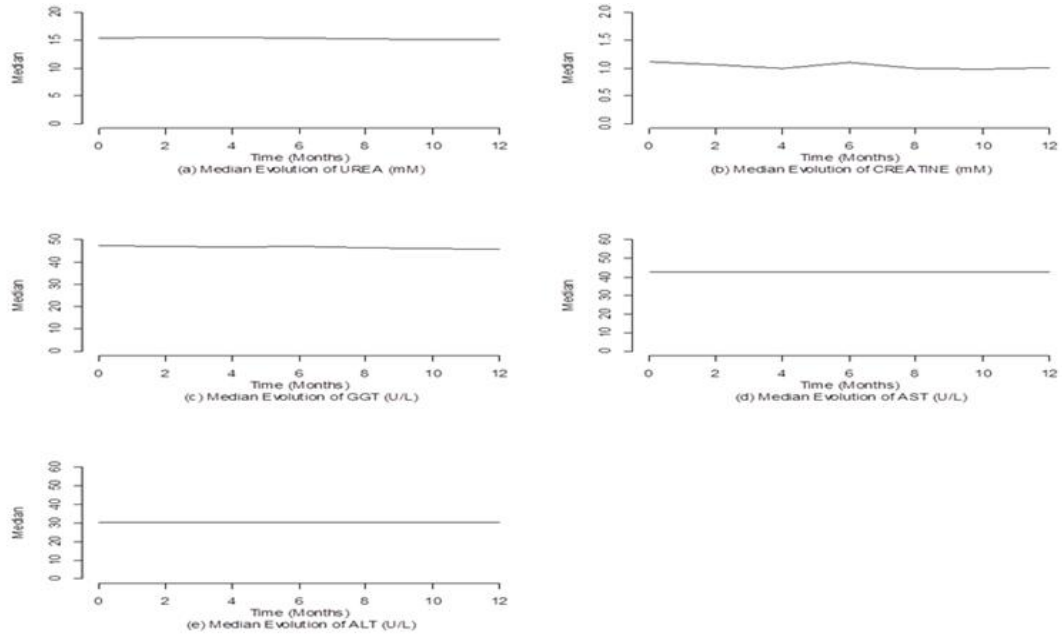



Phenotypic changes in females & in males

Effects of Virad and IMB on Immunological Parameters: The trends of immunological parameters CD4, CD8 and CD4/CD8 ratio increased while viral load decreased significantly. CD4 cells increased by 15.67 cells /mm3 per month. The CD4 counts differed by baseline characteristics, a unit difference in age resulted in a difference of CD4 by 0.22 cells /$mm^3$, older patients having higher counts and females recorded higher CD4 cell counts by 82.56 cells /$mm^3$ compared to their male counterparts. CD4 count of 800 to 1200 cells /$mm^3$ isconsidered to be the normal ranges. In this study CD4 cells for males and female patients increased from 290 to 420 cells / mm3, by a total of 130 cells /mm3 at end of the study.




Effects of Virad and IMB on Biochemical parameters: The Kidney and Liver parameters Urea, creatine, gamma guanidine amino transferase (GGT), Aspartate aminotransferase (AST) and Alanine amino transferase (ALT) did not significantly increase over time. Individuals exhibited different readings at baseline. AST measurements differed significantly by gender while ALT differed significantly by both age and gender. The normal ranges of ALT for males are 10 to 55µ/l, females 7 to 30u/l. The individuals GGT (U/L) profile exhibited universal leveled progression with very minimal fluctuation between the 4th and the 8th months. Some individuals had a sharp reduction at the 2nd to the 4th months followed by a gradual not so significant decline to the 12th month. GGT for Male and female patients had minimal decline. The average changes for GGT (U/L) exhibited a leveled profile parallel to X axis with very slight drop.Effects on Kidney Parameters: During treatments, there were no significant changes, but there was an overall reduction by 0.2mg/dl. Normal range of Urea in male patients is 36 to 85 µmol /l, and of Females is 23 to 66µmol/l. The average urea level for patients was 15mg/dl to 14.8mg/dl. The individual Urea profiles (mM) exhibited no significant changes for the majority of participants (p=0.05).




Biochemical parameters (Average Evolutions)

## IV. Discussion

This study provided information on characteristics of patients living with HIV/AIDS, their phenotypic body mass indexes (BMI), Hematological and Immunological properties, liver and Kidney parameters, their changing features as the participants took herbal formulations Virad and IMB to mitigate viral complications. The representative sample (n= 188) of patients from 18 years to over 65 years both male and female from Mombasa county. Sixty six percent (66%) were female and 34% were male. Females were double the number of males, and their modal age range was 31 to 40 years with median of 37 years. This was consistent with the study by Stephen and Nancy, (1999) that reported increasing infection rates in females, where more women than males were dying of HIV/AIDS. Also consistent with argument by UNAIDS, (2010) this was prime age forming the bulk of Kenyan work force and most active sexually and probably formed the age group that carried the highest burden of HIV infection and with highest rate for HIV infection and transmission.Ninety eight percent (98%) of participants were at stages II and III. The complications associated with these stages and related psychological issues could have dictated HIV patients to seek treatments from herbal practitioners and would most likely suggest patients were anxious and required psychological assurance. It was on this psychological anxiety basis that groups of HIV + persons are encouraged to join up with groups that would assure prolonged life.This study isolated curative phyto-components including Phenolic acids, Saponins, Tannins, Alkaloids, Flavonoids, Protein and Lipids, at different proportions in the herbal formulations Virad and IMB. Some studies by Izadoost and Robinson, (1987), and Gonda (1992); argued that herbs relied for their effects on a variety of constituents and the idea of synergy within them was gaining acceptance. Their additive or synergistic effects could have contributed to therapeutic evidence seen in the patients of this study.According to Sofowra (1993); Phenolic acids (hydroxybenzoic and hydroxycinnamic acids) synthesized by plants during development in response to disease infections, posses' biological properties such as antiappoptosis, antiaging, anticarcinogenic, antiinflammation, antiatherorosclerosis, cardiovascular protection and improvement of endothelial function, and Inhibit cell proliferation activities.Okwu and Josiah (2006) described Saponins to stop bleeding, treat wounds and ulcers and helped in red blood cell coagulation. Aslam and Shaw, (1991); discussed Saponins to have inhibitory effect on HIV replication as HIV protease enzyme inhibitors and helped in red blood cell coagulation, inhibited viral DNA synthesis. Gonda et al., (1992); discussed ursane type saponinsto interfere with the formation of capsidal proteins.Vlientinck et.al, (1998): described Tannins to have properties of astringency and HIV reverse transcriptase inhibition. Astringent medicines caused shrinkage of mucous membranes or exposed tissues and when used internally they checked discharge of blood serum or mucous secretions. This happens with a sore throat, hemorrhages, diarrhea, or with peptic ulcers. Also, Tannins have styptic effect preventing apoptosis and lysis of infected cells crucial in progression of HIV /AIDS.Mathee and colleagues (1999); described Alkaloids such as of castanospermine contain Michelin A-B and C, to have a broad range of anti-HIV activity. Aslam and Shaw, (1991); described Alkaloids in gossypol and Tylosemato provide HIV protease and HIV- induced cytopathogenicity. Periwinkle indole alkaloids possess antineoplastic effects, antiluekaemic and vasodilator and antitumor properties and inhibit development of malignant conditions (Aslam and Shaw, 1991), which are a common phenomenon in HIV/AIDS compromised cases.Del-Rio and colleagues (1997); flavonoids increased appetite for human nutrition and health. Another similar study by Okwu, (2004), and by Zhou, (2000): Flavonoids contain hydroxyl functional groups, responsible for antioxidant effect and inhibit HIV reverse transcriptase and HIV replication in HG lymphocyte. They inhibit giant cell formation in HIV infected cell cultures.The presence of Potassium, Sodium, Calcium, Magnesium, Iron, Zinc and Copper micronutrients in Virad and IMB added the therapeutic potentials required for treatment in this study. In consistent with studies by Papadopoulos, (1988); patients that had subclinical deficiencies of trace elements and vitamins were at risk of impaired immune function and hence an increased risk of infection.Before the uptake of Virad and IMB, 98% of the patients had BMI that was less than $18kg/m^2$ a highly significant independent predictor of mortality. At baseline 61.5% of patients had abdominal hyperacidity with ulcers known to limit food uptake and affecting the general nutritional status of patients, and this affected weight and BMI (IRIN, 2009). According to Cunning-ham (2000), weight loss was a common problem in HIV, and patients were frequently found to have abnormalities of plasma mineral and trace element concentrations, especially of zinc, selenium and magnesium. uptake of Virad and IMB, weights and BMI gained significantly ($P < 0.05$), with difference of 16kg in weight and BMI by 4.8kg/m2 and this prolonged patient's survival.In established HIV infection, lower hemoglobin levels correlated with decreasing CD4+ cell counts and similar study by Lau et al. (2005), found association between anemia during established infection and a faster progression to AIDS and death. The immune booster IMB contained neem leaf extracts consistent with the study of Udeinya et al., (2003) which noted that neem leaf extracts improved patients, increasing hemoglobin, platelet count, CD4+ cell count and body weight.A study by Lanzillotti and Tang (2005) showed that Low blood concentrations of many micronutrients were common in HIV-positive individuals and were associated with disease progression and in-creased mortality. Virad and IMB contained spectra of antioxidant micronutrients including zinc which contributed to the therapeutic effects seen in this study.There was increase in CD4 and mitigation of CD8 counts. The CD4/CD8 ration increased and the

viral load reduced significantly ($p< 0.05$). These results showed there was strengthened immunity for the patients in this study, because of the increase in CD4 T cells, reduction in CD8 T cells, and an increase in CD4/CD8 ratio, that resulted into a significant reduction in viral load ($p< 0.05$). According to Shaninian et al. (2000); people with HIV/AIDS risk developing kidney disease because of the progression of the AIDS virus and the side effects of the medicines they may be taking to slow this progression, although it still ranked relatively low in the order of individual causes of death. It was evident that Urea levels among takers of Viard and IMB reduced by 0.1 mM. For the male patients, urea values did not show any change while in females Urea levels decreased by 0.1 mM. There was evident decrease for Creatinine in both male and female patients. There were no adverse effects in using these herbal therapies at least for the period of this study. In this case phenolic acids were not able to change the status of the kidney despite being known to be active in curing kidney and stomach problems and helpful as anti-inflammatory in action (Marjorie, 1996), but Phenolic acids may have protected the kidney from injury and dilapidating effects of the HIV/AIDS viral progressions.In this study the liver parameters were all reduced by 0.3 U/L. In both male and female patients liver parameters, gamma glutamyltransferase (GGT) recorded some reduction. It is possible Virad and IMB provided protective mechanism for the liver, presence of silimarin (Flavonoids) components in IMB that fortify the liver could have protected the liver and prevented possible damage. According to Kren et al., (1998), Morazzoni and Bombardelli, (1995): Flavonolignans found in Silimarin compounds exert antihepatotixic activity preventing galactosamine induction of cell lesions, hence were hepatoprotective and antagonized liver degenerative mechanism. Despite the presence of Flavonoids known to mitigate ailments of the liver, the values were not significant ($p=0.05$), but more important to safeguard the liver cells from damage.Conclusions Based on these study findings, Virad and IMB were effective and safe, raised BMI, improved immunity, reduced viral burdens and did not present toxic effects on Kidney and Liver.The isolated phytochemicals and minerals, in Virad and IMB provided healthcare and prolonged life.

## V. Conclusions

i. Flavonoids, Alkaloids and lipids were of highest concentrations in these formulations.
ii. Immunological factors CD4/CD8 were raised; viral burdens reduced therefore improved immunity and were efficacious.
iii. Liver and kidney functions were not adversely altered; these phytochemicals were not toxic and therefore safe for use.

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IOSR Journal of Pharmacy and Biological Sciences (IOSR-JPBS) is UGC approved Journal with Sl. No. 5012, Journal no. 49063.

Mwavita A. L "Efficacy and Safety of Herbal Formulations Used For Management of Hiv/Aids In Mombasa County." IOSR Journal of Pharmacy and Biological Sciences (IOSR-JPBS) 13.1 (2018): 27-35.