TITLE

EFFECTIVENESS OF SYNDROMIC MANAGEMENT OF VAGINAL DISCHARGE AT SPECIALIZED TREATMENT CENTER (CASINO) NAIROBI.

A dissertation submitted in part of fulfillment of Masters of Medicine in Obstetrics and Gynecology at University of Nairobi.

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DECLARATION

I hereby declare that this research study in part of fulfillment of M.MED degree in Obstetrics and Gynecology is my original work under the guidance of my supervisors and has not been presented before for a degree course to any other University.

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DEDICATION

I dedicate this study to my wife Laura and our children Kiri and Mwisho for their unwavering support and prayers throughout my postgraduate studies. To my parents and siblings for the big role they played in helping me achieve my dream.

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LIST OF ABBREVIATIONS

BV-Bacterial Vaginosis.

CBD-Central Business District.

CDC-Centre of Disease Control.

C.Trachomatis-Chlamydia Trachomatis.

HIV-Human Immunodeficiency Syndrome.

HVS-High Vaginal Swab.

MCS-Microscopy, Culture and Sensitivity.

NAAT-Nucleic Acid Amplification Test.

PCR-Polymerase Chain Reaction.

PID-Pelvic inflammatory Disease.

STI-Sexual Transmitted Infection.

TV-Trichomonas Vaginalis.

UTI-Urinary Tract Infection.

UON-University of Nairobi.

WHO-World Health Organization.

ABSTRACT

BACKGROUND: Syndromic management is a World Health Organization (WHO) strategy for the management of Sexually Transmitted Infections (STI). Diagnosis is based on identification of syndromes, which are combinations of symptoms as reported, by client and signs observed during examination. Syndromic management is recommended for STI management in developing countries especially where laboratory facilities are unavailable. Etiological diagnosis of STI is problematic in many settings. It places constraints on time, resources, costs and access to treatment. In addition, the sensitivity and specificity of available tests can vary significantly, thus, affecting negatively, the reliability of laboratory testing.

OBJECTIVE: The study was aimed to determining the effectiveness of the currently recommended kit for syndromic management of vaginal discharge among women attending at specialized treatment center casino.

METHODS: A quasi-experimental study (pre-post study design without a control group) was conducted from January 2012 to march 2012, a nonrandom convenience sampling was used and a total of 100 women were recruited, 3 women were not able to return for the second visit. The study used structured questionnaire pre and post treatment and laboratory methods (High vaginal swab and endocervical swab for microscopy, culture and sensitivity both on day one before treatment and day eight after treatment with the kit to measure effectiveness of the syndromic management .A kit containing 2grams of Secnidazole, 150mg of fluconazole and 1gram of Azithromycin was used as an intervention on day one.

RESULTS: The results of 97 women who completed the study, showed the effectiveness of syndromic management of vaginal discharge using the current recommended kit was 79.4%.Bacterial Vaginosis was the commonest microbe found in women presenting with vaginal discharge followed by Vaginal candidiasis at 28.9%,Trichomonas vaginalis 7.2%,Staphylococcus Aureus 3.1%(probably contamination) and no growth obtained 24.7%.

CONCLUSION: The effectiveness of syndromic management of abnormal vaginal discharge at specialized treatment center (Casino) using the current recommended kit was 79.4%.

RECOMMENDATION: The combination kit therapy in syndromic management of vaginal discharge allows simple, fast and assured therapy with a high cure rate. Its use turns out to be cost effective and should be highly recommended especially in poor resource settings.

CHAPTER 1: INTRODUCTION AND LITERATURE REVIEW

INTRODUCTION: Vaginal discharge is one of the most common problems in women coming to gynecological outpatient clinics accounting for over 10million visits per year in U.S.A.[1]Trichomonas vaginalis, bacterial vaginosis, vulvovaginal candidiasis are the most common causes of pathological vaginal discharge.[1] However cervicitis caused by gonorrhea and Chlamydia trachomatis also cause vaginal discharge but to a lesser extent.Vaginal discharge may be physiological or pathological. Although abnormal vaginal discharge often prompts women to seek screening for sexual transmitted infection, vaginal discharge is a poor predictor of Sexual transmitted infection. The etiology of vaginal complains includes infection of the vagina, cervix and upper genital tract, and a number of noninfectious causes, such as reactions to allergens and irritants (e.g. spermicides, douches, laundry and hygiene products), foreign bodies, estrogen deficiency and rarely systemic diseases. In 1998.World Health Organization introduced the concept of Syndromic management due to its advantages namely:

(I)Easy to use.

(II)Allows immediate treatment initiation.

(III)It's highly sensitive and doesn't miss mixed reactions.

(IV)It provides the opportunity to discuss risk reduction, condom promotion and compliance.

(V)Inexpensive-no laboratory investigations.

In syndromic management, diagnosis and treatment is not based on specific diseases indentified by testing but rather on syndromes, which is a group of clinical findings. Treatment is generally given for all or at least most commonly seen diseases that could cause that syndrome. The global burden of STI and especially in sub Saharan Africa where Kenya is a member state, the syndromic approach has turned out to be useful in reducing the impact of HIV pandemic. Untreated sexually transmitted disease is more prone to disease spread and runs a higher risk of contacting HIV.Chamydia increases replication of HIV; gonorrhea helps excretion of HIV in semen, while trichomoniasis and bacterial vaginosis facilitate HIV transmission and acquisition. Thus sexually transmitted disease increase the risk of HIV by 10 fold.[1] The current standard syndromic approach has been used in most resource limited set ups compared to laboratory diagnosis which is time consuming, expensive and many a times unavailable. Thus it has become necessary to treat vaginal discharge as a syndrome rather than an individual disease. Appropriate drugs should be chosen, which effectively cover all the organisms causing vaginal discharge, preferably in a single kit which is commercial available in

Kenya containing 2grams of secnidazole, 1gram of Azithromycin and 150mg of fluconazole to ensure patient compliance. Both trichomoniasis and bacterial vaginosis can be treated with secnidazole given as a single stat dose of 2grams, has better tolerability and patient compliance. It has a larger half life and a longer duration of action. It is more cost effective with less adverse effects compared to Metronidazole given for five days.Fluconazole has increased acceptance and it is the only oral drug recommended by center for disease control USA in a single start dose of 150 milligrams.[2]It is well tolerated and cost effective unlike vaginal creams or suppositories containing clotrimazole or miconazole, which are often inconvenient and unacceptable due to various cultural, religious and social factors. Chlamydia and gonorrhea are routinely treated with tetracycline or penicillin group of antibiotics, which is given in multiple doses. This causes poor patient compliance and missed doses leading to relapse. However with the advent of Azithromycin macrolide, a single dose of 1gram has excellent cure rates of 90-100%.[2]It is important to treat these two diseases in vaginal discharge, as 70% of Chlamydia and 30% of gonococcal infections are asymptomatic and remain undected in women.[2] Due to its wide spread use, hence the need to assess its effectiveness in management of vaginal discharge.

Normal vaginal physiology and flora

In women of reproductive age normal vaginal discharge consists of 1 to 4ml of fluid per 24hrs, which is white or transparent, thick and mostly odorless. This physiologic discharge is made up of mucoid endocervical secretions in combination with slough epithelial cells, normal bacteria and vaginal transudates. The discharge may become more noticeable during pregnancy. The PH of the normal vaginal secretions is 4.0 to 4.5.The acidic environment is hostile to growth of pathogens and inhibits adherence of bacteria to vaginal squamous epithelial cells. Microscopic examination reveals a predominance of squamous cells and rare polymorph nucleus leukocytes.[2]

The microbiology of the vagina is complex containing ten bacterial colony forming units per gram of secretions and potentially dozen of different isolates. The most abundant normal isolates are lactobacillus which produces hydrogen peroxide and lactic acid thereby maintaining the normal acidic vaginal PH diphtheroids and S.epedermidis.[2] Age, phase of the menstrual cycle, sexual activity, contraceptives choice, and pregnancy, presence of necrotic tissue or foreign bodies and use of hygienic products or antibiotics can disrupt the normal ecosystem. In premenarchal and postmenopausal women in whom estrogens levels are low, vaginal epithelium is thin and the PH of normal secretions is 4.7 or more, which is due to reduced colonization of lactobacilli.[3]

Trichomoniasis Vaginalis:

Trichomonas vaginitis is the causative agent, it accounts for 4 to 35 percent of vaginitis diagnosed in symptomatic infections in reproductive aged women in U.S.A and increases with age.[4]The responsible organism is the flagellated protozoan Trichomonas vaginalis, which may be found in the vagina, urethra and Para urethral glands of infected women. Other sites include cervix, bartholin's and skene's glands, humans are the only natural host of T.V.The incubation period is unknown, however in vitro studies suggest an incubation period of 4 to 28 days. Classic signs and symptoms include a purulent malodorous thin discharge with associated burning, pruritus, dysuria, frequency and dyspareunia.Postcoital bleeding can occur. The urethra is also infected in majority of women, symptoms may be more during menstruation. The classically described green, frothy and foul smelling discharge is found in fewer than 10 to 30% of symptomatic women.[1] Physical examination often reveals erythema of the vulva and

vaginal mucosa, punctuate hemorrhages may be visible on the vagina and cervix (straw berry cervix).

Complications:Trichomoniasis is a risk factor for development of post hysterectomy cellulitis, tubal infertility and cervical neoplasm, premature rupture of membranes, preterm labour and also it facilitates transmission of human immunodeficiency virus.

Diagnosis:

(I)Microbiology and PH: The presence of motile trichomonads on wet mount is diagnostic of infection, but this occurs in only 50 t0 70% of culture confirmed cases.[2]Theorganism remains motile for10 to 20 minutes after collection of sample.

(ii)culture: culture on diamond medium has a high sensitivity and specificity and should be considered in patient with elevated vaginal PH. Increased number of polymorph nucleus leukocytes and in absence of motile trichomonads and clue cells on wet mount.

(iii)Rapid antigen and nucleic acid applications test: These test are useful in areas of high prevalence where microscopy on culture is not available.

(iv)Cervical cytology:Trichomonads are sometimes reported as an accidental finding on conventional papanicolaou smear. This technique has a sensitivity of 51 to 63% false positive are common.[2] Pap smear should not be used to diagnose trichomoniasis.

Treatment: The 5-nitro imidazole drugs (metronidazole or imidazole are the only class of drugs that provide curative therapy of trichomoniasis.[5]

Chlamydia Trachomatis

It's the most common bacterial agent of sexually transmitted genital infection. A significant proportion of patients are asymptomatic, thereby providing an ongoing reservoir for infection. Infants born to mothers through an infected birth canal, conjunctivitis and pneumonia can occur.[6]

Microbiology:C.trachomatis is a small gram negative bacteria with unique biologic properties that distinguish it from all other living organism. It is an obligate intracellular parasite that has a distinct life cycle that consists of two major phases (reticulate body and elementary bodies. Chlamydia cannot be cultured on artificial media; traditionally tissue culture has been required to establish a diagnosis. One clinical feature of chlamydial organism is that immunity for infection is not long lived. As a result reinfection or persistent infection is common.[6]

Epidemiology :Approximately four million cases of C. trachomatis infection are estimated to occur annually in the U.S.A making this the most common STD.Chlamydia trachomatis and Neisseria gonorrhea cause similar clinical syndromes, but chlamydial infections tend to have fewer acute manifestation more significant long term complications. The prevalence of chlamydial infection is 4.2%.[6]

Risk factors for infection are: Adolescent and young adults, Multiplesex partners or a partner with other partner, Inconsistent use of barrier contraceptives, Cervical ectopy and history of prior sexually transmitted disease. Clinical manifestation: Although the majority of women with C.trachomatis infection are asymptomatic, clinical manifestation ranges fromcervicitis to pelvic inflammatory disease. The incubation period of symptomatic disease ranges from 7 to 14 days.[7]

(I)Cervicitis-In women cervical infection is the most common chlamydial syndrome.

(ii)Dysuria-Pyuria syndrome to urethritis often accompanies cervicitis. Women with urethral infection often complain of typical symptoms of U.T.I.

(iii)Perihepatits (Fitzhugh-Curtis syndrome)-occasionally patient develops perihepatis an inflammation of the liver capsule and adjacent peritoneal surfaces, commonly seen in PID.

(iv)PID-Approximately 30% of women with chlamydia infection will develop PID if left untreated PID caused by Gonorrhea infection may be more acutely symptomatic.[7] PID due to C.trachomatis tends to be associated with higher rates of subsequent infertility.[8]Diagnosis: Noninvasive screening options such as urine testing or self collected vaginal swabs are more acceptable to patients and require fewer resources.

(I)Culture-culture methods are limited to research and reference laboratories due to its expense. It should be used routinely only in case of forensic investigations like rape or child abuse.

(ii**)**Nucleic amplification-Nucleic acid amplification(NAAT) methodology consist of amplifying C.trachomatis DNA and RNA sequences using PCR,transcription mediated amplification or strand displacement ampilification.These sensitive and specific test have replaced poorly standardized cell culture methods as the gold standard and are preferred diagnostic markers. Another advantage of NAAT is the ability to perform testing on urine as well as urethral specimen.

(iii)Antigen detectio**n**-Antigen detection requires invasive testing using swabs from the cervix or urethra.

(iv)Genetic probe methods-Genetic probe method requires invasive testing using a direct swab.

(v)Chlamydia rapid testing-Rapid testing provide results within 30 minutes of testing and are less expensive to perform and simple to interpret since testing results are reflected in a test strip color change.[8]Treatment: Azithromycin 1g per oral as a single dose and doxycycline 100 mg per oral twice a day for seven days are the two recommended regimes.

Neisseria Gonorrhea

It remains a significant cause of preventable and treatable morbidity in women. Several studies have evaluated the relationship between the number of exposure and the rate of infection. The most concerning complications of gonorrhea relate to female production. The resultant scarring from PID may lead to infertility or ectopic pregnancy.[9] Women may also infect their newborns infants with Gonorrhea during birth causing neonatal opthalmia.Clinical presentation-Gonorrhea in women can involve any portion of genital tract. Infection in women is often asymptomatic compared to men who are asymptomatic in only 10% of the time.[10]Cervical infection-It is the most common site of mucosal infection with Gonorrhea, 50% of the infected women are asymptomatic.[11] Symptomatic infection typically manifest as vaginal pruritus or mucopurulent discharge. The cervical mucosa is often friable and evidence of concurrent upper genital tract disease may be present.Urethritis-Gonococcal urethritis can occur in the absence of PID and is responsible for up to 10% of cases of dysuria among urban women.[11]Anorectal infection and proctitis-Anorectal gonococcal infection can be asymptomatic or associated with clinical proctitis.Pharyngeal infection-Gonococcus isolated from the oropharynx typically represents asymptomatic colonization, although symptomatic pharyngitis can also occur. Other mucosal sites of infection are bartholins glands and skene's gland which can also become infected with Gonorrhea in women. Pelvic inflammatory disease-PID occurs in approximately 10 to 40%

of women with cervical gonorrhea. Gonorrhea is estimated to be the causative organism in 40% of cases of PID.[12]Diagnosis-The diagnosis of gonorrhea in women is somewhat more complex than in men due to more invasive and less accurate methods of sampling Gonorrhea.

(I)Culture: The gold standard for diagnosis of gonorrhea was culture using a modified Thayer-Martin medium. Cultures from endocervical specimen are quite sensitive for diagnosing gonorrhea in symptomatic women but only 65 to 85% sensitive in asymptomatic infection.[13]

(ii)Gram stain: The use of gram stain for the diagnosis of cervical gonorrhea, which appear as intracellular gram negative diplococcus is only 60% sensitive in symptomatic women compared with 95% in symptomatic men.[13]

(iii)Enzyme immunoassay:EIA was developed to detect gonococal antigens from cervical swab or urine specimens but is not widely used because it's positive predictive value is only acceptable in populations with high prevalence of infection.

(iv)DNA probe:DNA probe are approved for diagnosis of gonorrhea from end cervical swabs.DNA probes labeled with a chemi-luminescent marker identify a specific nucleic acid sequence of the organism.

(v)DNA amplification techniques**:** Compared to culture commercially available nucleic acid amplification test(NAAT) Offer rapid results within hours but are more expensive.NAAT methodology consist of amplifying N.gonorrhea,DNA or RNA sequence using polymerase chain reaction, transcription mediated amplification(TMA) or strand displacement amplification(SDA).Treatment: Increasing antimicrobial resistance has rendered the treatment of uncomplicated gonococal infection more complex. Gonorrhea has demonstrated increased resistance to a variety of agents including penicillin, tetracycline and ciprofloxacin. Due to rising rates of resistance CDC no longer recommends the use of fluoroquinolones.Azithromycin 1g orally once or doxycycline100mgorally twice a day for seven days are suitable regimes. Ceftriaxone125 mg IM start or cefixime 400 mg start.[14]

Bacterial Vaginosis

Bacterial vaginosis is the most common cause of abnormal vaginal discharge in women of childbearing age, accounting for 40 to 50% of causes.[14] The worldwide prevalence ranges from 11 to 48% of women of reproductive age with variations according to the population studied.[14] The absence of inflammation is the basis of the term vaginosis rather than vaginitis.Pathogenesis and microbiology: Bacterial vaginosis is not due to a single organism, instead it represents a complex change. In the vaginal flora characterized by a reduction in concentration of the normally nominal hydrogen peroxide producing lactobacillus and an increase in concentration of other organism especially anaerobes. These include gardenella vaginalis,mycoplasma hominis,prevotella species,porphyomonas species,bacteroids species and atopobium vaginae.Hydrogen peroxide producing lactobacilli appear to be important in preventing overgrowth of the anaerobes normally present in the vaginal flora with loss of lactobacilli,PH rises and massive overgrowth of vaginal anaerobes occurs. Risk factors: For acquisition of BV include multiple or new sexual partners, douching and cigarette smoking, although sexual activity is a risk factor for the condition, BV can occur in women who have never had vaginal intercourse. Clinical features: Approximately 50to 70% of women with are asymptomatic.[15]Those with symptoms present with an unpleasant "fishy smelling" discharge that is more noticeable after coitus.The discharge is of white, thin and homogenous. Dysuria and dyspareunia are rare; while pruritus, erythema and inflammation are typically absent.BV can be associated with cervicitis.Diagnosis: The diagnosis of BV is based on clinical findings and laboratory. Three of the four Amstel criteria listed below are necessary for diagnosis, although the first three findings are sometimes present in patients with trichomoniasis.

(I)Homogenous, thin, greenish-white discharge that smoothly coats the vaginal walls.

(ii)Vaginal PH greater than 4.5.

(iii)Positive whiff-amine test defined as the presence of a fishy odor when 10% potassium hydroxide is added to a sample of vaginal discharge.

(iv)Clue cells on saline wet mount.

The presence of clue cells diagnosed by experienced microbiologist in the single most reliable predictor of BV.Clue cells are vaginal epithelial cells studded with adherent coccobacilli that are best appreciated at the edge of the cell.Using a gram stain as the gold standard, the sensitivity of Amstel criteria is over 90%.[15]Gram staining of vaginal secretions is a reliable method for diagnosis of BV ,but is mostly performed in research studies because its more cumbersome to use in clinical practice than Amstel criteria.Vaginal culture has no role

in diagnosis because there are no bacteria that are specific for BV, although cultures for G.vaginalis are positive in almost all women with symptomatic infection.DNA probes for G.vaginals are expensive and suffer from the same limitation as culture, but provide fairly quick results and may be useful to practitioners unable to perform microscopy. Diagnostic cards(e.g. femcard,quickvue,pip activity test card) are rapid test for confirming the clinical suspicion of BV.The papanicolaou smear is not reliable for diagnosis of BV (sensitivity 49%, specificity 93%).[16]

Complications of BV:

i. Pregnant women with BV are at high risk of preterm delivery.
ii. There is a casual relationship between BV and endometrial bacterial colonization, plasma cell endometritis, postpartum fever, post hysterectomy vaginal cuff cellulitis and post abortal infection.
iii. Bacterial vaginosis is a risk factor for HIV acquisition and transmission, herpes simplex virus type II, gonorrhea and chlamydial infection.
iv. Bacterial vaginosis is more common among women with PID.

Treatment: BV resolves spontaneously in up to one third of nonpregnant and one half of pregnant women.

i. Metronidazole or Clindamycin administered either orally or intravaginally will results in a high rate of clinical cure. Oral medication is more convenient but associated with a higher rate of systemic side effects than vaginal administration.
ii. Tinadazole is a second generation Nitromidazole.It has a longer half-life than Metronidazole and fewer side effects.

Vaginal candidiasis

It accounts for approximately one third of vaginitis cases unlike trichomonas vaginitis; it's not considered a sexually transmitted disease.Prevalance**:**Candida species are part of the lower genital tract flora in 20 to 50% of healthy asymptomatic women.[17]Vulvovaginal candidiasis is common in adults and less common in postmenopausal women, unless they are taking estrogen therapy.[18]Microbiology and pathogenesis: Candida albicans is responsible for 80 to 92% of the episodes of vulvovaginal candidiasis.[19] Candida organism probably access the vagina via migration across the perianal area from the rectum. Cultures of gastro intestinal tract and vagina often show identical candida species. The mechanism by which candida species cause symptomatic disease is complex involving host inflammatory response to invasion and yeast virulence factors (e.g. elaboration of proteases).

Risk factors:

i. Diabetes mellitus- Women with poor glycemic control are more prone to vulvovaginal candidiasis than euglycemic women.
ii. Antibiotics-Women are prone to vulvovaginal candidiasis during or after taking broad spectrum antibiotics.
iii. Increased estrogen levels-Vulvovaginal candidiasis appears to occur more often in the setting of increased estrogen level such as oral contraceptives.
iv. Immunosuppression-More common in immunosuppressed patients such as those taking corticosteroids or with HIV infection.
v. Contraceptives devices-Vaginal sponges, diaphragm and intra uterine devices have been associated with vulvovaginal candidiasis but not consistently.

Clinical features: Vulvar pruritus is the dominant feature of vulvovaginal candidiasis women may also complain of dysuria, soreness, irritation and dyspareunia. The discharge is classically described as thick, adherent and cottage cheese like. Physical examination often reveals erythema of the vulva and vaginal mucosa and vulva edema. Diagnosis: The vaginal PH is typically 4 to 5 which distinguishes candidiasis from trichononiasis or BV,The clinical diagnosis should be confirmed by finding the organism on a wet mount of the discharge adding 10% of potassium hydroxide destroys the cellular elements and facilitates recognition of budding yeast and hyphae.Microscopy is negative in up to 50% of patients with confirmed vulvovaginal candidiasis.[20]Culture is not recommended routinely because its costly, delays the time to diagnose and may be positive due to asymptomatic colonization. Treatment: A variety of oral and vaginal preparations available over the counter and in single dose regime are available for the treatment of vulvovaginal candidiasis.

Study justification

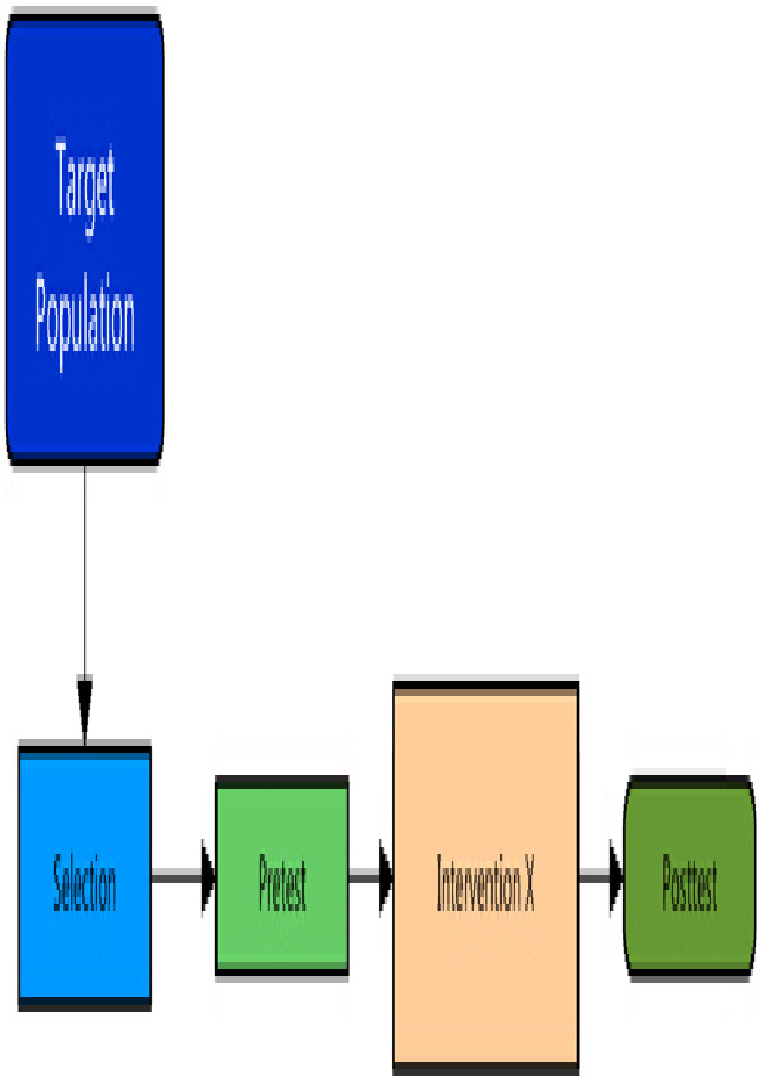
Vaginal discharge is often polymicrobial and treatment of only one or the most apparent cause may lead to a flare up and clinical manifestation of the other cause. Thus it's important to treat vaginal discharge as a syndrome rather than a single most clinically apparent cause or disease. Combination kits are cheaper, effective given in a single dose orally which allows good compliance, complete treatment at the first visit, thus preventing the spread of STI and HIV which is a pandemic in sub-Saharan Africa. Research has proven that adequate treatment of symptomatic STI reduces HIV transmission.[5]

The other regime used for treatment of vaginal discharge based on laboratory diagnosis have proven to be costly and time consuming due to the fact it involves HVS for m/c/s and PCR etc. which are expensive tests and the patient has to wait for some days for the result thus making the patient to stay without treatment while awaiting for results.

Null hypothesis

There is no difference in the microbial pattern before and after treatment with the kit among women with vaginal discharge.P value > 0.005 will be significant.

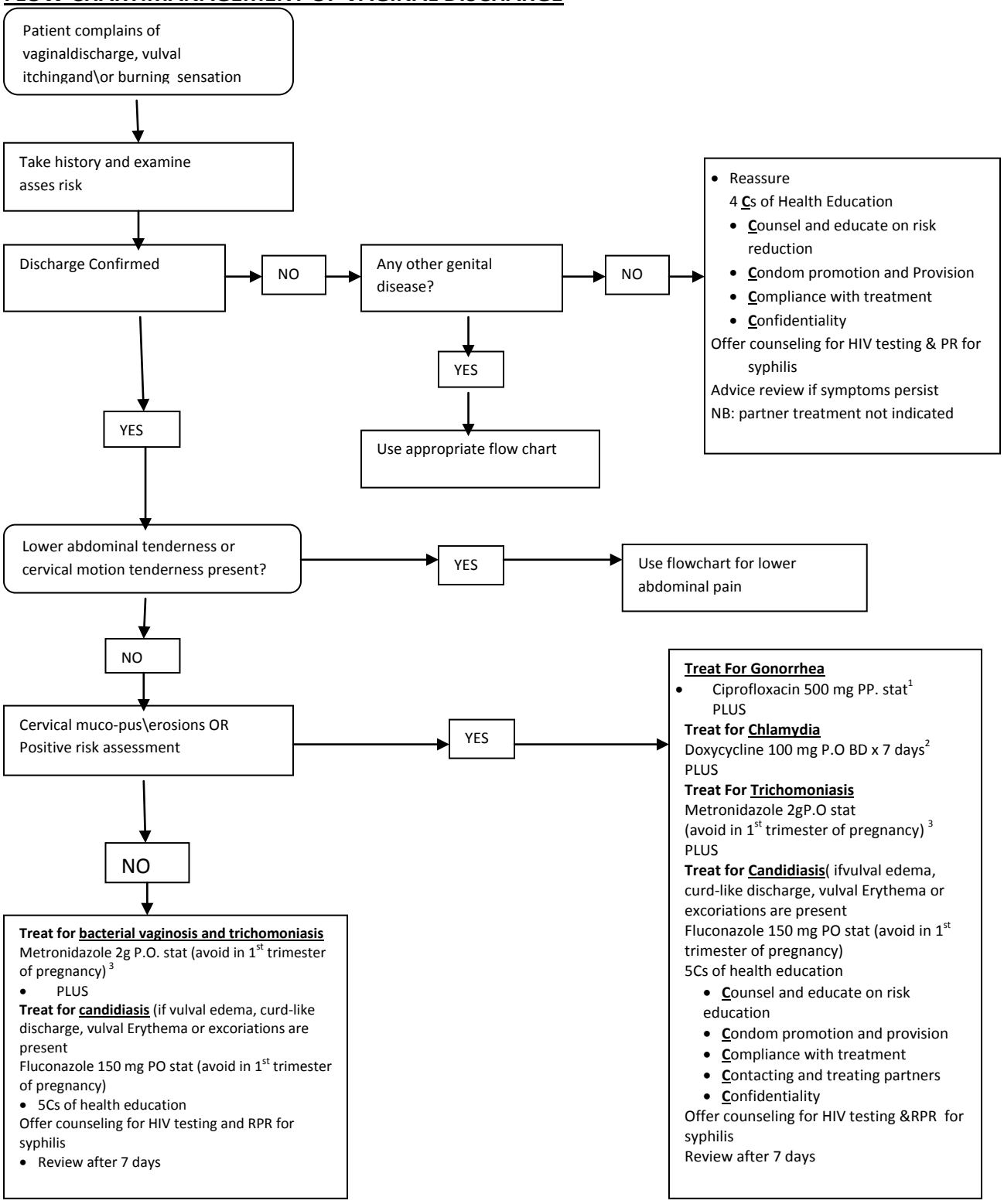
FIGURE 1 . CONCEPTUAL FRAME WORK



Target population-women presenting with abnormal vaginal discharge. Selection-Participants meeting the inclusion criteria. Pretest-Day one laboratory(HVS and endocervical swab for microscopy, culture and sensitivity).Intervention-Kit containing 2gram of secnidazole ,1gram of Azithromycin and 150mg of fluconazole.Posttest-laboratory tests on day eight as day one.

FIGURE 2.

FLOW CHART.MANAGEMENT OF VAGINAL DISCHARGE



Positive Risk Assessment

Consider RISK ASSESSMENT POSITIVE in **sexually active** clients with atleast one of the other risk factors listed below.

- Multiple sexual partners in the previous three months
- Having a new partner in the previous three months
- Having a current partner with an STI
- Victim of sexual assault
- Inappropriately treated STI's

Research question

What is the effectiveness of the currently recommended kit for syndromic management of vaginal discharge at Specialized Treatment Center Casino?

Broad objective

To determine the effectiveness of the currently recommended kit for syndromic management of vaginal discharge.

Specific objectives

1.To determine the effectiveness of syndromic management of vaginal discharge.

2. To determine the microbial pattern among women who present with vaginal discharge.

3. To determine complications associated with the kit used for syndromic management.

CHAPTER 2:METHODOLOGY.

Study design

Quasi-Experimental Study: Pre-post test design study without a control group[21]

Study setting

The study was carried out at Specialized Treatment Center Casino. The health facility is located in Nairobi CBD area under the management of Nairobi city council. It deals mainly with treatment of sexual transmitted disease, skin diseases and other common ailments. Its clients are mostly low income earners and commercial sex workers, thus providing it as the best place to carry out the study. About 100 both new and old patients are seen and treated on a daily basis. It offers medical services from Monday to Friday starting from 8 am to 5 p.m.They use laboratory based investigations as their protocol for treating vaginal discharge.

Study population

Female clients above 18 years old presenting with abnormal vaginal discharge at Specialized Treatment Center Casino.

Inclusion criteria

i. Clients presenting with abnormal Vaginal discharge at Specialized Treatment Center Casino, who are above 18 years.
ii. Informed written consent.

Exclusion criteria

i. Pregnant mothers (Oral Fluconazole and Secnidazole are contraindicated in pregnancy).
ii. Allergic to any of the study drugs.

Women not eligible or who declined to participate in the study were treated according to the protocol in the health facility.

Sample size

In calculating the sample size,open Epi epidemiology calculator software was used, accessed from www.openEpi.com.A prevalence of 13.5% of abnormal vaginal discharge was used from a study done in west Africa[12] . Using fleiss with continuity correction formula a minimum total sample size of 100 was arrived at to achieve a 95% confidence interval.

Sampling technique

A nonrandom convenience sampling of the first 100 consenting patients with abnormal vaginal discharge were recruited from January 2012 to March 2012.

Screening and recruitment

The principal investigator with the assistance of a trained study nurse reviewed all patients as they came to the observation area .Those that satisfied the study criteria were informed about the study and those willing to participate were considered eligible. Eligible clients were called one by one into the consulting room. The screening provider went through the information on the consent form regarding relevance of the study, questionnaires, physical examination and specimen collection. Willing clients then signed or thumb printed the consent form. No study procedures were conducted before informed consent was provided by clients.

Clinical procedures

Participants were interviewed using a questionnaire to gather socio-demographic and relevant information such as history of current symptoms, antibiotic use within the last two weeks, and allergy to any of the study drugs. After which the study physician conducted general physical examination, gynecological examination and prescribed the kit for the participants after taking HVS and endocervical swab for M/C/S sample in the presence of a female chaperone.

Laboratory specimens

High vaginal swab for M/C/S as specimen A and endocervical swab for M/C/S as specimen B using a Dacron swab.

Procedure for specimen collections

The clients were provided with additional counseling to ensure that they were comfortable prior to collection of the laboratory samples. The principal investigator and in the presence of a female nurse chaperone, requested the client to lie in the semi-lithotomy position. While at the foot of the bed , with good lighting and putting on a pair of sterile latex gloves, the study physician examined the external genitalia and then parted the labia with the left hand to access the vaginal introitus.Two sealed sterile Dacron swab were be used to swab the higher vagina and endocervix with speculum placement. The swabs were placed immediately into a labeled Stuart's transport media without charcoal (Biotech laboratory ltd.38 Amson Road Marteshan Healths).The transport media maintained the microbial viability for up to four days at room temperature or eight days under refrigeration. Specimens label indicated participant's serial number. It also clearly identified that specimens were for HVS and endocervical swab for

M/C/S.The specimen were taken to UON obstetrics and gynecology department laboratory within 24 hours.

Laboratory techniques.

The specimens were received and processed at the UON Obstetrics and Gynecology department laboratory as per their SOP below. The laboratory currently offers a wide variety of microbiological cultures including aerobic and anaerobic bacteriology.

Wet preparation

Mounted the sample on the slide and put a cover slip. Observed the slide under X 10, and then under X 40 magnification (to look for pus cells, yeastcells, bacterial vaginosis or Trichomonas vaginalis among other cells like bacteria cocci, lactobacillietc)

Culture

Cultured the sample on Thayer-Martin medium (TM) for isolating N.gonorrhea(sample was put at edge of the plate then using a wire loop it was streaked using the zigzagpattern.Incubated the place anaerobically at 37 C for 18-24hr and observed for any colony growth.

STAINING PROCESS

Smear preparation

Using a wire loop a drop of water was picked and put on the slide.Sterilzed the wire loop and picked the grown colonies at the edges of stricking lines. Prepared the smear by spreading the colonies on the drop of water avoiding a very thick smear. Heat fixed the smear by passing the over gas flame but avoided over heating the slide.

Staining

Flooded the smear with crystal violet stain and leaved it for 30-40 seconds.

Poured off excess stain and flooded with 4% gram iodine and allow for 30 seconds. Washed off with running tap water and added 1 % ethanol and allowed for a few seconds, poured off and washed with tap water. Flooded with Safranin stain and allowed for 30 seconds and washed off the slide and put it upright to dry.

Microscopy

Observed the smear under oil emersion (X 100) microscope magnification, once identified to be bacterial pathogen proceeded to drug sensitivity.

Sensitivity

Used a cotton swab to spread the colonies on nutrient agar plate or MH medium.

Place the drug disc avoiding them to be close to one another and Incubated overnight and observed any growth inhibition. Classified the magnitude of inhibition by measuring the diameter of zone of inhibition.

Data collection

A total of 100 consenting women above the age of 18 years with a history of abnormal vaginal discharge were recruited to the study, their symptoms and gynecological history was collected using a pretested coded questionnaire to gather socio-demographic, other relevant history, findings on physical examinations were documented. The principal investigator or research nurse carried out a gynecological examination and type of discharge was noted. All participants were prescribed two doses of one day combination kit, one dose was for their partners. Each kit contained Secnidazole 2grams, Fluconazole 150 mg and Azithromycin 1gram, which is the national recommended treatment, after HVS and endocervical swab for M/C/S sample were taken by the Principal Investigator or the Research nurse on day one. They were requested to take these tablets on the same day with their partners after meals and abstain from sex or use condoms for seven days, subsequently they were reviewed on day eight with empty packets of the tablets to confirm that they took medication. Effectiveness was assessed by symptomatic response and laboratory results based on a repeat HVS and endocervical for M/C/S on day eight. Those who did not respond to treatment were recommended specific treatment based on laboratory results. Patients not following up or not taking the prescribed treatment were excluded from the study. Participants were contacted on day seven through their mobile phone numbers and reminded to come for review on day eight.

Quality assurance

Two nurses working at Specialized Treatment Center Casino were trained as research assistants. Clinical and laboratory diagnostic criteria for the purpose of this study were laid down for the sake of uniformity in filling the questionnaire.

Data management and analysis

Questionnaires were stored under lock and key before and after data entry. The database was restricted from access using a password. Once data entry was completed, data cleansing was done by checking each data against the hard copy forms. Missing values, range checks and inconsistency in the data was done using an automated program during data entry using EPI-INFO and a Statistical Package for Social Scientist (SPSS-version 16).

Ethical considerations

Participation in the study was voluntary and no incentives were given. No client was denied care or their case prejudiced if they declined participation. Clients were given written and oral explanation of what the study entails, its potential benefits and dangers (allergic reactions to the drugs and treatment failure) by the principal investigator and research assistants and consent to participate in the study were sought.

A female nurse (chaperone) was present during physical examination. No name identifiers were placed on study materials in order to protect client's privacy.

Benefits to subject

The clients did not pay for any drugs and laboratory charges.

Study limitations.

1. Lack of a control arm and randomization was a major limitation due to the nature of our study design.

2. Laboratory diagnosis tests limitation (Chlamydia antigen or PCR) for diagnosing Chlamydia trachomatis.

CHAPTER 3: RESULTS

RESULTS

108 women were evaluated for inclusion into the study.7 declined consent for the study and 1 was excluded due to language barrier. 100 women completed questionnaires and examination and were initiated on syndromic management Kit as per protocol. 97(97%) of the women returned for follow up visit and completed the second part of the study. Two of the women who did not return could not be reached by phone while the third had travelled and could not make it for reevaluation within the period of the study.

SOCIO-DEMOGRAPHIC AND OBSTETRICS DATA

Table 1 show that majority of the subjects (58.8%) were between the ages of 20 – 29 years, followed by (34.2%) 30 – 39 years. A sample population of 3.9% were 19 years and below with only 3.1% representing women who are 40 years and above. Data also reveals that most of the subjects (50.5%) were married followed closely by (47.4%) who are single; with only 2.1% who were widowed or separated. The education level; most of them (47.4%) education level was up to secondary with 3.1% attaining college/university education. A significant number of subjects (48.5%) had completed primary education with 1% representing those with no formal education.

Table 1: Age, Socio-demographic and obstetrics variables

Age n=97	**<19years n=4(3.9%)**	**20-29years n=57(58.8)**	**30-39years n=33(34.2%)**	**>40years n=3(3.1%)**
Educational level				
Primary n=47(48.5%)	1(2.1%)	28(59.6%)	16(34%)	2(4.3%)
Secondary n=46(47.4%)	3(6.5%)	28(69.9%)	15(32.6%)	0(0%)
College/ University n=3(3.1%)	0(0%)	1(33.3%)	1(33.3%)	1(33.3%)
Marital status				
Married n=49(50.5%)	0(o %)	14(28.6%)	33(67.3%)	2(4.1%)
Single n=46(47.4%)	4(8.7%)	42(91.3%)	0(o %)	0(0%)
Widowed/Separated n=2(2.1%)	0(0%)	1(50%)	0(0%)	1(50%)
No of children				
O n=29(29.9%)	2(6.9%)	11(37.9%)	16(55.2%)	0(0%)
<1 n=27(27.8%)	1(3.7%)	18(66.7%)	7(25.9%)	1(3.7%)
>1 n=41(42.3%)	1(2.4%)	28(68.3%)	10(24.4%)	2(4.8%)
Menstrual cycle				
Regular n=47(48.5%)	2(4.3%)	30(63.8%)	15(31.9%)	0(0%)
irregular n=37(38.1%)	2(5.4%)	22(59.5%)	11(29.7%)	2(5.4%)
Amenrrhoiec n=7(7.2%)	0(0%)	5(71.4%)	1(14.3%)	1(14.3. %)

Most of the subjects (42.3%) had more than one child while 29.9% of them had no children. The remaining 27.8% of them had just one child. Table 1 also illustrates that 48.5% of the subjects had regular menstrual cycles while 38.1% had irregular ones. 7.2% of the respondents were amenorrhoeic. The rest of them did not give a response. Most of the respondents (35%) did not use any kind of contraceptives. 6.2% of them used the most ineffective form of contraceptive - natural methods. On the other hand, 24.7% used injectables (Depo-Provera) while 11.3% had implants. 7.2% of them used condoms while the same number used intrauterine contraceptive devices. The remaining 9.3% used combined oral contraceptive pills.

Subject's Symptoms - Colour of Vaginal Discharge, Symptoms summary and Speculum exam of the Vaginal Discharge

92% of the respondents had normal external genitalia and 8% had abnormal external genitalia; i.e. they were either swollen or presenting with lesions. Besides this observation, the first symptom to be analysed was the colour of the subject's vaginal discharge and as seen in table 3; 54.6% of the subject's vaginal discharge was white in colour while 33% of them had yellowish discharge and 3.1% had greenish discharge. 9.3% of the respondents' vaginal discharges were other colours e.g. brownish. The results for symptoms are as shown in table 3: 62.9% of the subjects vaginal discharge had a foul smell, . 76.2% of them had Pruritus Vulvae and 54.6% experienced pain while having sex. 57.7% of the subjects complained of lower abdominal pain and the same number reported frequency in urinating and dysuria. The results of the speculum examination showed that 60.8% of the respondents had curd like vaginal discharge some with eroded cervix; 34% had cervical mucopus while 5.2% had frothy vaginal discharge.

Table 2: Colour of Vaginal Discharge, Symptoms Summary and Speculum exam of the Vaginal Discharge n=97

Vaginal discharge	
White	53(54.6%)
Yellow	32(33%)
Greenish	3(3.1%)
Others	9(9.3%)
Symptoms	
Foul smelling	61(62.9%)
Pruritus	74(76.2%)
Dyspareunia	53(54.6%)
LAP	56(57.7%)
Urinary symptoms	56(57.7%)
Speculum examinations	
Mucopus	33(34%)
Curd like	59(60.8%)
Frothy	5(5.2%)

DETERMINING THE EFFECTIVENESS OF SYNDROMIC MANAGEMENT OF VAGINAL DISCHARGE.

Table3: Evaluation of Symptoms' Response to Medication N=97

Response of symptoms to medication	Good Response	Some Response	No Response
Abnormal vaginal Discharge N=97(100%)	67(69.1%)	23(23.7%)	7(7.2%)
Itchiness of the Vulvae N=72(74.2%)	61(84.7%)	9(12.5%)	2(2.1%)
Pain while having Sex N=51(52.6%)	41(80.4 %)	6(11.8%)	4(7.8%)
Lower Abdominal Pain N=54(55.7%)	35(64.8%)	16(29.6%)	3(5.6%)
Pain while Passing Urine (dysuria) N=56(57.7%)	55(98.2%)	1(0.8%)	0(0%)

The microbial pattern among women presenting with Abnormal Vaginal Discharge:

Laboratory Test Results for Pre-treatment and Post treatment (Follow-Up) For Specimen A (HVS for M/C/S):

The results are as shown in table 4. 24.7% respondents' vaginal discharge exhibited no growth obtained. On the other hand 36.1% exhibited Bacterial Vaginosis; 28.9% respondents had Candida Albicans and 7.2% exhibited Trichomonas Vaginitis. The remaining 3.1% exhibited Staphylococcus Aureus (contamination). As shown in the same table there was a significant improvement in patients conditions when they were tested during follow up. It was noted that the overall number of subjects who had no growth obtained increased from 24.7% to 75.3%. This is mainly because all respondents who had Trichomonas vaginitis were no longer presenting with the pathogen. The same conclusion could be made when it came to Bacterial Vaginosis, 36.1% of respondents who were presenting with the pathogen, 27.9% were now pathogen free. Furthermore, out of 28.9% of patients presenting with Candida Alibicans, 18.3% were no longer presenting with the pathogen. However 3.1% more of the respondents presented with Staphylococcus Aureus after treatment bringing the total to 6.2% of respondents with the pathogen.

Table 4: Lab Test Results For Specimen A (HVS for M/C/S) N=97

Initial Pathogen Isolated	**Prior Treatment _ No. Of Patients Presenting With Pathogen 73=75.3%**	**Follow Up After Treatment_ No. Of Patients Presenting With Pathogen 24=24.7%**	**P-value**
Trichomonas Vaginitis	7(7.2%)	0%	0.003
Bacterial Vaginosis	35(36.1%)	8(8.2%)	0.002
Candida Albicans	28(28.9%)	10(10.3%)	0.003
Staphylococcus Aureus	3(3.1%)	6(6.2%)	0.001
Overall No growth obtained	24(24.7%)	73(75.3%)	0.004

Laboratory Test Results For Pre-treatment and Post treatment For Specimen B (Endocervical Swab for M/C/S)

In the post treatment evaluation, as in pretreatment no growth was obtained for N.Gonorrhea or C.Trachomatis.

DETERMINING THE COMPLICATIONS ASSOCIATED WITH THE KIT USED FOR SYNDROMIC MANAGEMENT

Subject's Side Effects to the Medication

12.4% of the respondents complained of persistent nausea after taking the drugs and another 10.3% of the respondents complained of having metallic taste. 9.3% complained of having epigastric discomfort while 8.2% of them had headaches. Finally 6.2% had skin rashes or pruritus and 4.1% complained of dizziness and vomiting. However it should be noted that 45.4% subjects had no side effects at all. NB: All the drugs in the kit have been noted to cause more or less the same minor side effects.

Table 5: Side Effects to the Medication

Side Effects to the Medication	**N=97(100%)**
No side effects at all	(44)45.4%
Nausea	(12)12.4%
Metallic Taste	(10)10.3%
Epigastric discomfort	(9)9.3%
Headaches	(8)8.2%
Skin Rashes or Pruritus	(6)6.2%
Dizziness And Vomiting	(4)4.1%
No Response	(4)4.1%
Total	**100%**

CHAPTER 4: DISCUSSION.

Since Poor adherence to treatment regimens has long been recognized as a substantial roadblock to achieving better outcomes for patients, it was important to ensure that all the respondents had followed the instructions they were given to take the drugs and well enough, ninety eight percent (98%) of the respondents said they had taken the medication as advised, showing good drug adherence. The study set out to determine the effectiveness of of syndromic management of vaginal discharge in women presenting with abnormal vaginal discharge using the current recommended kit (containing 2grams of secnidazole, 1gram of Azithromycin and 150mg of fluconazole) at specialized treatment center (Casino). Effectiveness was assessed by symptomatic response and laboratory results based on a repeat HVS and endocervical for M/C/S on day eight. Our results showed the effectiveness of syndromic managentment to be at 79%, which was similar compared to a prospective study done by shailesh.k et al in India however their study never in cooperated the laboratory investigations. Also a randomized control trial done in west Africa by Jacques Pepin et al comparing single dose treatment using Tinadozole plus fluconazole(TF) with treatment for 7 days with metronidazole plus 3 days of treatment with vaginal clotrimazole(MC) found complete resolution in 66%(TF) and 64% in the (MC) arm. The leading microbes causing abnormal vaginal discharge as per HVS results were bacterial vaginosis at 36.2%,Candida albican 28.9%,Trichomonas Vaginalis 7.2% and S.Aureus which was observed in 3% of the patients arose probably from contamination.24.7% of the subjects had no growth obtained in there lab samples, this could have been due to, no microbes were actually cultured or limitations in the lab diagnosis.Vishwanath.S et al syndromic management of vaginal discharge in a reproductive clinic in India found the prevalence to be 26% for bacterial vaginosis,12.2% for C.trachomatis,10% for trichomoniasis and no N.gonorrhea isolated which were less similar with our results apart for the C.trachomatis.Most of the comparable studies have shown Candida albican to be the leading cause of vaginal discharge. The endocervical swab results on both day one and day eight no microbes were isolated (Chlamydia trachomatis and N.gonorrhea were 0%); this was attributed to the limitation on lab diagnosis because the current recommended diagnostic test is Chlamydia antigen. On how well the participant's abnormal vaginal discharge responded to medication, 69.1% felt they had a good response while 23.7% of them felt that there was some response and 7.2% had no response. Itchiness of the Vulvae response to medication, 84.7% of them felt they had a good response, 80.4% of the subject's also admitted that their dsypareunia had a good response to the medication while 7.8% said there was no response at all. As for lower abdominal pain, 64.8%said that they had good response while 29.6% said that they had only some response. As for dysuria,98.2% of them said they had a good response and 1% said they had some response.Also this was a quasi-experimental pretest-posttest without a control arm, we lacked a comparison group and we nonrandomized the participants The vaginal discharge is often polymicrobial in nature. When any of these three drugs is used individually, the desired effect may or may not be achieved due to diversity of pathogenic agents .Combination kits are cheaper, effective, given in single dose orally with effectiveness of 79.4%.Treating only women for vaginal discharge leads to inadequate treatment and relapse, as most of the etiological causes of vaginal discharge are sexually transmitted, it is logical to treat both partners. In this

study we gave therapy to both the partners[1].Syndromic management has many advantages over conventional methods. It greatly reduces dependence on laboratory tests. In resource limited countries like Kenya, laboratory testing may be too expensive diagnostic and are often unavailable. Even where laboratory diagnosis is available, it is time consuming and often does not correlate with clinical findings. Also syndromic approach greatly simplifies diagnostic complex process for health workers without medical skills or experience. The most important benefit of syndromic management is that treatment begins immediately, patient acceptance and compliance is good. Immediate treatment increases the chance of successful care and reduces the time interval during which the infection can spread. The single dose combination kit allows good compliance, complete treatment at the first visit thus preventing the spread of sexually transmitted disease and HIV.[2]

CONCLUSSIONS.

The effectiveness of syndrome management of vaginal discharge at the specialized treatment center (casino) using the current recommended kit was 79.4%.

RECOMMENDATIONS.

The combination kit therapy in syndromic management of vaginal discharge allows simple, fast and assured therapy with a high cure rate. Its use turns out to be cost effective and should be highly recommended.

References:

1. WHO guidelines for management of STI Geneva, WHO/HIV-AIDS/2001.1.

2. STI. Syndromic approach to STD management, sex transm infects 1998:74(suppl 1).

3.Fonck,Kidula N,Jaoko w.et al.Validity of vaginal discharge algorithm among pregnant and non pregnant women in Nairobi Kenya.Sex Transm infect 2000;78:30-38.

4.Kalil R .Kimani J,Fonck, Ngugi et al monthly antibiotic chemoprophylaxis and incidence of STI and HIV-1 infection in Kenya sex workers.A rct JAMA 2004;291:255-66 .

5.Kamali A, Quigley M,Makiyingi J .et al syndromic management of STI and behavior change intervention on transmission of HIV-1 in rural Uganda. A community randomized trial lancet 2003;361:645:52.

6.WHO training modules for the syndromic management of STI2nd ed.8v.2002.1

7.Watson EJ,Templeton A,Pussel, et al .The accuracy and efficacy of screening test for Chlamydia trachomatis, systemic review J med micro bio,(2002)51:1031-103.

8.Gupta V,acute PID an overview, Indian journal of obstetrics and gynecology 2000: 3.35.

9.Dallabata GA, lerbase AC, Holmes KK problems solutions and challenges in syndromic management of STD .sex transm INF 1998:74(suppl 1):51-11.

10.Gross K H, Mosha F, Mwijaribu E et al.Impact of improved treatment of sexually transmitted diseases on HIV infection in rural Tanzania. Lancet 1995,346:530-6.

11.Latif syndromic management of STD.Central Africa journal of medium 1998 44:206.

12.Pepin J,sobala F ,Alary M, et al low prevalence of carried infections in women with vaginal discharge in west Africa, implications for syndromic management,sex transm infect 2004;80:230:-5.

13.Waver MJ, Sewankombo NK, Kiwanuka N. et al control of STD for mob prevention in Uganda: A rct lancet 1999;353:525:-25.

14.Patel KU, Sheriar NK, Walurker VR.Journal of obstetrics and gynecology India.1994;44:122.

15.Mehta SD,Kriegler JN,Achola-Ndinya et al monitoring of Syndromic management of STD 1996 Vol 4 NO2.

16.Prashin, Moodly,Stum AW ,et al. Management of vaginal discharge syndromes.Kwa Zulu Natal 2004 vol 24 supp1.

17.Boonstra E,Linda Back M,Koulman E,et al.Syndromic management of sexually transmitted disease in Bostwana's Primary Health care:quality of care aspects.Trop Med Int Health 2003;8:60414.

18.Mbofana F S,Brito F J,Safodina A,Cliff JL.Syndromic management of sexually transmitted diseases at primary care level,Mozambique.Sex Transm infect 2002;78:E 1-2.

19.Martin D,Kuoman E,Masatu M;Clinician perspective on training programme in syndromic management of sexually transmitted infections in Northern Tanzania.Int J STD AIDS 2006;16:697-701.

20.World Health Organization Guidelines for the management and treatment of sexually transmitted disease,2003.http://WWW.Who.int/reproductive-health/publication/mngt_stis/(accessed 8 Jan 2008).

21. Anthony D. H,Douglas D. B, Mona B, etal The Use and Interpretation of Quasi-Experimental Studies in Infectious Diseases. Clin Infect Dis 2004.

APPENDIX I: PATIENT INFORMATION AND CONSENT

Investigator's statement

We are requesting you to be in a research study. The purpose of the consent form is to give you the information you will need to help you decide whether to be in this study. Please read this form carefully. You may ask questions about what we ask you to do, if there is any risk, your benefits, your rights as a volunteer, or anything else about the research or anything in this form that is not clear. When all your questions have been answered, you can decide if you want to be in this study or not. This process is called informed consent.

Back ground information

Vaginal discharge is one of the most common and nagging problems faced by women. Bacterial vaginosis, Trichomonal vaginitis, Gonorrhea, Chlamydia and vaginal candidiasis are the most common causes of pathological vaginal discharge. Though in a few cases discharge may be physiological ,increase in normal vaginal secretion. Many a times this infection are sexually transmitted .Untreated or under treatment of sexually transmitted disease is more prone to disease spread and runs a greater risk of contracting HIV.

Why is the study being done?

This study will help us find out how effective is syndromic management using the current recommended kit, containing grams of Secnidazole, 1gram of Azithromycin and 150 mg of fluconazole among women presenting with vaginal discharge at specialized treatment center (casino).If we find the treatment is effective we shall advocate for it to be adopted as the first line treatment for vaginal discharge.

Study procedure.

If you agree to participate, a medical history and physical examination will be done .This will entail inquiring about your age, history of the current vaginal discharge. In the presence of a female nurse (chaperone) the doctor will collect one swab from you (higher vagina after inserting a speculum into your vagina).The speculum and swabs for collecting specimens are sterile and the procedures are non-traumatic. You will be informed about the results of the tests during your next visit, which will be after seven days and it will be shared with your primary care physician for intervention where appropriate.

Confidentiality

All information obtained will be strictly confidential and will not be revealed to any other persons, other than your primary care physician. The quality of care given to you in this hospital will not be compromised by your refusal to participate in this study. Participation in this study is voluntary (at your own will you are free to participate or to withdraw at any time).100 women will take part in this study. Two visits will be required for the research, day one will entail HVS for M/C/S specimen being taken, prescription of the kit and on day eight you will be shown the results of the test and be assessed if you responded to the treatment.

Benefits.

(i) You will not pay for any laboratory charges.
(ii) You will not pay for any drug charges.
(iii) If you will not respond to the treatment, we shall recommend the appropriate treatment based on the lab results on day eight.

Risks

By participating in this study no risk to you are anticipated.

Signatures

_____

Investigators signature and date

Subject statement.

I_____of_____hereby without enticement or coercion understand the above (purpose andbenefits of the study) and agree to give my consent to participate in this study.

_____

Subjects signature or (thumb print) Date

In case of any queries or further information, please contact the following persons.

Investigator Title institution

DR.Oyiengo Vincent Principal investigator UON

Supervisors

PROF.J.B.O. Oyieke Supervisor UON

DR.Lubano Kizito supervisor KEMRI/UON

Principal investigator contact: 0721976187.

Or

The Chairman of KNH/UON-ERC

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APPENDIX II

PATIENTS QUESTIONNAIRE

EFFECTIVENESS OF SYNDROMIC MANAGEMENT OF VAGINAL DISCHARGE AT SPECIALIZED TREATMENT CENTER CASINO Nairobi?

Study number_____ clients mobile NO [_____]

Date of interview (day/month/year) ___/___/___

***A* Socio-demographic data**

1. Age ____years
2. Marital status {1][2][3] (1) married
   (2) Single
   (3) Widow/Separated

3. Level of education [1] [2] [3] (1) primary

   (2) Seco ndary

   (3) College/University

B.Obstetrics and gynecological questions.

1. Parity Para___+___
2. L.M.P ___/___/___
3. Cycle[1][2](1) regular (2) irregular
4. Contraceptive use [1][2][3][4][5][6]
   (1)Iucd (4) Implant
   (2) Coc (5) Condoms
   (3) Injectable (depo) (6) Natural
5. History of STD [1][2](1) Yes (2)No

C.Risk assessment.

1. How many sexual partners have you had in the last three months? [1][2][3]

(1) Multiple (2) One (3) None

2.Have you had a new sexual partner in the last three months? [1][2]

(1)Yes (2) No

3. Do you have a current partner with S.T.I? [1][2] (1) Yes (2) No

4. Are you a victim of sexual assault? [1][2] (1) Yes (2) No

5.Have you been treated previously for S.T.I? [1][2] (1) Yes (2) No

6.Lower abdominal tenderness on examination. [1][2] (1) Yes (2) No

D. Symptoms

1. What is the colour of the vaginal discharge? [1] [2] [3] [4] (I) yellow

(2)Whitish

(3)Greenish

(4)Others specify____

2.Does the discharge foul smell? [1][2] (1) Yes (2) No

3. Do you have pruritusvulvae (itching of the genitals)? [1][2] (1) Yes(2) No

4-D you havedyspareunia (pain while having sex)? [1][2](1)Yes(2) No

5. Do you have lower abdominalpain?[1][2](1) Yes (2) No

6. Do you have urinary symptoms (frequency, pain while passing urine)? [1][2]

(1)Yes (2) No

7.Do you have an allergy to any of these drugs?[1][2][3][4]

(I) Azithromycin

(2) Fluconazole

(3)Secnidazole

(4) I have no allergy to any of the study drugs.

E.Speculum examination

1.Normal external genitalia?[1][2] (1)Yes (2)No specify_____

2.Type of discharge noticed.[1][2][3][4]

(1)Cervical mucopus

(2)Curd-like vaginal discharge

(3)Other abnormal vaginal discharge

(4)No abnormal discharge

E. Post treatment :Date___/___/___

1 Did you take the medication as advised? [1][2](1)Yes (2) No

2 Did the vaginal discharge respond to medication? [1][2][3]

(1) Good respon

(2) Some respons

(3) No response

3 Did the itchiness of the vulvae (pruritus vulvae) respond to medication? [1][2][3](1) Good response

(2) Some response

(3) No response

4 Did the pain while having sex (dyspareunia) respond to medication? [1][2][3]

(1) Good response

(2) Some response

(3) No response

5 Did the lower abdominal pain respond to medication? [1][2][3]

(1) Good response

(2) Some response

(3) No response

6 Did the pain while passing urine respond to medication? (1)(2)(3)

(1) Good response

(2) Some response

(3) No response

7 Did you have any of the following side effects? [1][2][3][4][5][6]

(1) Metallic taste (2) Nausea (3) Headache (4) Epigasric discomfort (5) Skin rash/pruritus (6) Any other specify

APPENDIX III: LABORATORY FORM(HVS AND ENDOCERVICAL SWAB FOR M/C/S)

Effectiveness of syndromic management of vaginal discharge at speciliased treatment center casino.

Study number_____

Date of specimen collection____/___/___

(a)SPECIMEN A(HVS for M/C/S)

(i)Pathogen isolated [1] [2] [3] [4] [5]

(1)T.vaginitis (2)B. vaginosis (3)C. albicans

(4)Others specify_____(5)No pathogen isolated

(ii)Sensitivity pattern [1] [2] [3] [4]

(1)Secnidazole (2) Azithromycin (3) Fluconazole (4) others specify_____

(b)SPECIMEN B (Endocervical swab for M/C/S)

(i)Pathogen isolated[1][2][3][4]

(1)C.trachomatis (2)N.gonorrhea (3)Others specify_____

(4)No pathogen isolated

(ii)Sensitivity pattern [1][2][3][4]

(1)Secnidazole (2) Azithromycin (3) fluconazole (4) Others specify_____

(C) Name of the lab technologist and signature

_____

APPENDIX IV:Maelezo na kibali cha kushiriki katika utafiti

SALAMU KUTOKA KWA MTAFITI

Tunawaomba mujiunge na utafiti huu.Madhumuni ya idhini ni kuwapatia maelezo ya kuwaezesha kuamua kujiunga au kutojiunga na utafiti huu.Tafadhali soma fomu kii kwa umakinifu.Unaeweza kuuliza maswali kuhusu tunayowaomba kufanya,kama kuna hatari yoyote.faida kwako,haki yako ya kujitolea ,kitu chochote kuhusu utafiti ama kitu chochote kuhusu hii fomu ambacho kina utata.Baada ya kuridhika kuwa hakuna utata wowote,utaamua kama wataka kuhusika na utafiti huu au la.Kitendo hiki kinaitwa kutoa idhini baada ya maelezo.

MAELEZO

Uchafu unaoshuka kutoka kizazi cha mwanamke ni moja katika shida zinazo sumbua wanawake.Uchafu wa ugonjwa unsababishwa na bacterial vaginosis,trichomonal vaginitis,gonorrhea na vaginal candidiasis.Kuna mara kadha uchafu uanaoshuka ni wa kawaida lakini mara nyingi uchafu unasababishwa na ugonjwa na kuna hatari zaadi ya kupata virusi vya ukimwi.

KWA NINI UTAFITI HUU UNAFANYWA

Utafiti huu utatusaidia kujua uwezo wa matibabu yanayopendekezwa kutibu uchafu wa uke.Matibabu ni ya aina tatu ya dawa gramu 2 ya secnidazole,gramu 1 ya azithromycin na miligramu 150 ya fluconazole.Tukipata kuwa matibabu haya yana uwezo kutibu,basi tutashauri kuchaguliwa kwa matibabu haya kama ya matibabu ya mwanzo kwa wenye uchafu wa uke.

UTARATIBU WA UTAFITI

Ukikubali kuhusika,tutachukuwa taarifa yako ya kiafya na tutakupima mwili,tutakuhoji kuhusu umri wako na uchafu unaoshuka kutoka kwa njia ya kizazi.Utasindikizwa na muuguza wakike halafu daktari atachukuwa uchafu kutoka njia ya kizazi akitumia vifaa maalumu.Vifaa hivi havina madhara yoyote.Utajulishwa majibu kuhusu uchafu sika ya saba baada ya matibabu.

UWEKAJI SIRI

Taarifa yote itakayo patikana itawekwa siri na haitafichiliwa kwa mtu yeyote isipokuwa Yule Yule tu daktari anaye kuhudumikia.Cheo cha huduma ya kimatibabu utakayopatiwa katika hospitali hii haitabadilika ukikataa kuhusika

katika utafiti.Kuhusika katika utafiti huu ni hiyari(yaani uko huru kuhusika ama kuamua kutoka wakati wosote ule).Wanawake mia moja watahusika kwenye uatafiti huu.Kutahitajika ziara mbili siku ya kwanza uchafu utachukuliwa na kupimwa baadaye utapewa dawa na siku ya nane utapewa majibu ya kipimo cha uchafu na kuulizwa maswali jinsi unavyo hisi baada ya matibabu.

MANUFAA

(i)Hutalipa gharama ya maabara.

(ii)Hutalipa gharama ya dawa.

(iii)Kama hutatibika baada ya matibabu,tutapendekeza dawa zifaazo kulingana na majibu ya maabara kwenye siku ya nane.

MADHARA

Hatutarajii madhara yoyote ukihusika kwenye utafutu huu.

SAHIHI

Sahihi ya mtafiti na tarehe

Mimi_____kutoka_____

Bila kushawishiwa au kulazimishwa na baada ya kufahamu maelezo(ya madhumuni na manufaa ya utafati)nakubali kutoa idhini nihusike kwenye utafiti huu.

_____ _____

Sahihi ama alama ya kidole cha gumba Tarehe.

Kama kuna swali au unataka maelezo zaida.Tafadhali unaruhusiwa kuwasiliana na watu wafuatayo

Mtafiti	**cheo**	**shirika**
Dr.Oyiengo Vincent	mtafiti mkuu	chuo kikuu cha Nairobi
Wasimamizi		
PROF.J.B.O Oyieke	msimamizi	Chuo kikuu cha Nairobi
DR.Luban KIzito	msimamizi	KEMRI/chou kikuu cha Nairobi

Mawasiliano ya mtafiti mkuu:**0721976187**

au

Mwenyekiti KNH/UON-ERC

Hospital Road.Sanduku ya anuani 20723 Nairobi

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APPENDIX V:MASWALI

NI UPI UWEZO WA MATIBABU YA SASA YANAYOPEDEKEZWA KUTIBU UCHAFU WA UKE KWENYE TAASISI YA MATIBABU MAALUM CASINO NAIROBI.

Nambari ya utafiti_____ mawasiliano ya mteja_____

Siku ya kuhojiwa___/____/____

A. MAELEZO KUHUSU MTEJA

1.Umri _____Miaka

2.Umeolewa[1][2][3] (1)Nimeolewa (2)Sijaolewa (3)Mjane/Tumeachana na bwana.

3.Kiwango cha elimu[1][2][3] (1) Shule ya msingi (2)Shule ya upili (3)Chuo/Chuo kikuu

B.Maswali kuhusiana na uzazi

1.Watoto waliozaliwa na mimba ziloharibika _____

2.Damu ya mwezi ___/___/____

3.Matumizi ya vikinga mwili[1][2][3][4][5][6] (1)coil (2)Tembe(3)Sindano(4)Implant (5)Mipira (6)Njia za asili

4.Umewahi kupata ugonjwa wa zinaa mbeleni?[1][2] (1)Ndio (2)La

5.Umekuwa na wapenzi wangapi wa ngono katika miezi mitatu iliiyopita?[1][2][3] (1)Wengi (2)mmoja (3) Hakuna hata mmoja

6.Je umekuwa na mpenzi mpya wa ngono katika miezi mitatu iliyopita?
[1][2] (1)Ndio (2)La

7.Kuna mpenzi yeyote wa sasa hivi ambaye ana ugonjwa wa ngono?

8.Je wewe ni mhadhiriwa wa kubakwa?[1][2] (1)Ndio (2)La

9.Je umewahi kutibiwa kwa ugonjwa wa zinaa mbeleni?[1][2] (1)Ndio (2)La

10.Maumivu kwenye sehemu ya chini ya tumbo.[1][2] (1)Ndio (2)La

C.Dalili za ugonjwa

1.Una uchafu wa uke wowote?[1][2][3][4] (1)Rangi ya manjano (2)Rangi nyeupe (3)Rangi ya kijani (4)Nyingine (fafanua)

2.Uchafu una harufu mbaya?[1][2] (1)Yes (2)No

3.Je una mwasho kwenye sehemu nyeti?[1][2] (1)Ndio (2)La

4.Je una maumivu wakati wa ngono?[1][2](1)Ndio (2)La

5.Je una maumivu kwenye sehemu ya chini ya tumbo?[1][2](1)Ndio(2)La

6.Je una dalili zozote za shida ya kukojoa(kukojoa mara nyingi,maumivu wakati wa kukojoa)?[1][2](1)Ndio (2)La

7.Kuna dawa zozote katika hizi zinazokudhuru?[1][2][3][4] (1)Azithromycin (2)Fluconazole (3)Secnidazole (4)Hakuna dawa zozote zinazonidhuru.

D.Baada ya matibabu

1.Je ulitumia dawa kama ulivyoagizwa?[1][2] (1)Ndio (2)La

2.Je uchafu wa uke umepona baada ya kutumia dawa?[1][2][3] (1)Umepona (2)Umepona kidogo (3)haujapona

3.Je mwasho wa sehemu ya nyeti umepona baada ya kutumai dawa?[1][2][3]
(1)umepona (2)umepona kidogo (3)haujapona
4.Je maumivu wakati wa gono ya metulia baada ya kutumia dawa?[1][2][3]
(1)yametulia (2)yametulia kidogo (3)hakuna tofauti
5.Je maumivu ya sehemu ya chini ya tumbo yameondoka?(1)yameondoka (2)yamepondoka (3)hayajaondoka.
6.Je uchungu wakati wa kukojoa umepotea?[1][2][3] (1)umepotea (2)umepotea kidogo (3)haujapotea
7.Je ulipata madhara yoyote kutokana na kutumia dawa kama?[1][2][3][4][5][6] (1)harufu mbaya mdomoni (2)kuhisi kutapika (3)kuumwa na kichwa(4)kusumbuliwa na tumbo (5)upele ama mwasho
(6)nyengine yoyote(fafanua)