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# **Assessment of Antibiotics and the Treatment of Sexually-Transmitted Diseases in Ghana**

**Final Report**

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March 22 - April 12, 1994**

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## EXECUTIVE SUMMARY

At the request of USAID/Ghana, a technical-assistance trip was made to Ghana by Dr Harold Davis of USAID/AFR/ARTS during March 22 - April 12, 1994. The purpose of the trip was to determine which drugs effective in treating sexually-transmitted diseases should be added to Ghana's Essential Drug List and National Formulary, a determination needed to establish conditionality for Non-Project Assistance in a new bilateral family planning and AIDS project.

The drugs (and dosage forms) that should be added to the Essential Drug List and National Formulary are ciprofloxacin (500 mg/tablet), ceftriaxone (250 mg/vial), doxycycline (100 mg/tablet or capsule), and clotrimazole (pack of 6 100-mg vaginal tablets). Ciprofloxacin and ceftriaxone are given in single-dose regimens to treat gonorrhea, which in Ghana is resistant to penicillin, tetracycline, co-trimoxazole, erythromycin, and spectinomycin. Ciprofloxacin, administered orally, should be the first-choice drug for gonorrhea, except in pregnant women and neonates with gonococcal ophthalmia, who should be treated with ceftriaxone. Doxycycline, taken twice daily, will enable far greater patient compliance with treatment regimens for chlamydia, now treated with tetracycline taken four times daily. Clotrimazole, used intravaginally once daily for three days to treat candidiasis, is much less expensive than miconazole and permits a much shorter treatment course than nystatin, which are the alternative drugs.

Median prices found in a survey of 16 retail pharmacies in Accra indicate gonorrhea could be treated with ciprofloxacin for \$2.31, chlamydia, with doxycycline for \$3.01, and candidiasis, with generic clotrimazole for \$2.15. Wholesale international-market prices, available when governments buy large quantities of drugs, indicate treatment of gonorrhea with ciprofloxacin would cost \$0.40, chlamydia with doxycycline, \$0.20, and candidiasis with clotrimazole, \$0.70. A previous analysis found that to avoid decapitalizing revolving drug funds, health facilities need to charge patients 2.5 to 3.1 times the wholesale international-market price.

If ciprofloxacin, doxycycline, and clotrimazole are used for gonorrhea, chlamydia, and candidiasis, at median retail-pharmacy prices syndromic treatment of urethral discharge would cost \$5.31, vaginal discharge in high-risk patients, \$7.70, and in other patients, \$2.39, genital ulcers, \$4.91, and lower abdominal pain, \$6.28. At wholesale international-market prices syndromic treatment of urethral discharge would cost \$0.60, vaginal discharge in high-risk patients, \$1.36, and in other patients, \$0.76, genital ulcers, \$2.01, and lower abdominal pain, \$1.05.

It is suggested that consideration be given to the following:

- o Funding meetings, travel, and certain other expenses required to enact changes in the Essential Drug List and National Formulary.

- o Establishing a conditionality that, after the recommended drugs are added to the Essential Drug List and National Formulary, the National AIDS Control Programme will revise its STD-treatment guidelines so that these are first-choice drugs
- o Establishing a conditionality that the STD-treatment guidelines in the Essential Drug List and National Formulary be revised to be identical to those of the National AIDS Control Programme, and that the revised Essential Drug List and National Formulary be printed and distributed to all health facilities
- o Funding activities to prevent and treat STDs in high-risk populations, including commercial sex workers and their clients. Currently, the Ministry of Health (MOH) does not have any such outreach activities. The activities should include counselling, provision of condoms, and syndromic treatment of STDs, with free or subsidized drugs provided by senior nurses at the workplaces of sex workers. By far, high-risk populations are the group in whom it is most cost-beneficial to prevent and treat STDs
- o Providing Public Health Reference Laboratories in Accra and Kumasi with the equipment and supplies for agar-dilution testing, the method recommended by the World Health Organization for surveillance of antibiotic-resistant Neisseria gonorrhoeae
- o Providing Noguchi Memorial Institute at the University of Ghana with equipment that will facilitate the freeze-drying of N. gonorrhoeae isolates resistant to ciprofloxacin, ceftriaxone, or norfloxacin. When more than 5% of isolates are resistant to any of these drugs, freeze-dried specimens should be sent to international reference laboratories for evaluation
- o If USAID decides to provide the materials needed for agar-dilution testing, then establishing a conditionality that the MOH will use the results of this testing to evaluate whether its STD-treatment guidelines should be changed
- o Funding operations research on the syndromic treatment of STDs, especially of vaginal discharge. Research should determine the validity of using risk assessment in the vaginal-discharge algorithm and how to improve risk assessment, accuracy of the algorithm for lower abdominal pain, quality of STD-case management, percent of patients who buy drugs prescribed, and percent of patients whose partners are notified and seek treatment
- o Conducting periodic surveys among well-defined groups to determine the incidence and prevalence of symptoms suggestive of STDs. Such surveys would be anonymous, to better elicit honest responses. A senior health official at Military Hospital (Accra) suggested doing such a survey on the 1,000 soldiers examined there every nine months prior to being sent to the United Nations Peacekeeping Force in Lebanon. Surveys also might be done among secondary-school students in the higher grades

## BACKGROUND/SCOPE OF WORK

USAID/Ghana is planning to initiate a new bilateral family planning and AIDS project, the Ghana Population and AIDS (GHANAPA) Program. This proposed project is a six-year, \$45 million combined project and Non-Project Assistance (NPA) program. GHANAPA has two components: family planning, and the prevention and control of acquired immune deficiency syndrome (AIDS), human immunodeficiency virus (HIV), and other sexually-transmitted diseases (STDs). The purpose of the program is to increase the use of modern and effective family planning methods, and to reduce the rate of increase of HIV prevalence.

The proposed NPA, totalling \$13 million in cash transfer assistance, will support significant policy reforms by the Government of Ghana to (1) increase the sustainability of family planning and AIDS/HIV/STD programs by increasing budgetary support, improving contraceptive pricing, forecasting and stocking procedures, and changing practices that impede family planning service delivery, and (2) improve services by increasing the availability of all contraceptive methods and selected drugs for treatment of STDs.

Proposed project assistance, including a \$20 million bilateral grant and \$12 million of OYB transfers for contraceptive procurement, will include technical assistance, training, commodities, and an endowment. The proposed project assistance is intended to (1) support policy and reform efforts, (2) increase demand for family planning, (3) expand provision of family planning services, (4) foster greater sustainability of family planning programs, (5) promote safe sexual behavior, (6) encourage proper diagnosis and treatment of STDs, and (7) improve the surveillance of AIDS/HIV/STDs.

The GHANAPA Program will work directly with public and private/non-government organizations to effect the desired changes in policy, demand generation, and delivery of services for both family planning and AIDS/STDs. The Program will fund training in the diagnosis and treatment of STDs of private physicians, nurse midwives, pharmacists, chemical sellers, and public-sector health personnel. For this training to have the desired public-health impact, drugs effective in treating the various STD syndromes need to be available to patients. In particular, drugs effective in treating the various STD syndromes need to be in the Essential Drug List and National Formulary, which influences decisions about which drugs are available to public-sector health facilities.

A trip to Accra, Ghana was conducted from March 22 to April 12, 1994 by Dr. Harold Davis, of the Bureau for Africa, U.S. Agency for International Development (USAID). The purpose of this trip was to determine which drugs effective in treating the various STD syndromes should be added to the Essential Drug List and National Formulary. This determination was to take into account drugs already in the Essential Drug List and National

Formulary, and also existing data on antibiotic resistance, drug costs, and the percentage distribution of STD syndromes presenting to public-sector health facilities

## FINDINGS OF THE ASSESSMENT

To accomplish the scope of work, a series of interviews, meetings, consultations, discussions, trip reports, official documents, and medical and public-health articles were held or reviewed. This report presents the findings of this assessment in the following sections:

- o Epidemiology of STDs in Ghana
- o Current treatment of STDs in Ghana
- o Syndromic approach to treating STDs
- o Status of Ghana's Essential Drug List and National Formulary
- o Recommendation for drugs to be added to the Essential Drug List and National Formulary
- o Cost of drugs for treating STDs in Ghana
- o STD-related activities of other donor organizations
- o Other recommendations on STD-related issues

## 1. Epidemiology of STDs in Ghana

Limited data are available on the prevalence of STDs in Ghana. In 1992, there were 15,000 cases of gonorrhea reported to the government. This figure probably represents only a small fraction of the actual number of new cases, as there are limited diagnostic capabilities, and many persons seek treatment for STDs from pharmacists, chemical sellers, or traditional healers, who are unlikely to report cases.

A study done at Korle Bu Hospital in Accra and published in 1985 indicated that gonorrhea and chlamydia infections were common among women. The study isolated Neisseria gonorrhoeae from five (3.4%) of 148 postpartum women and five (3.1%) of 162 randomly selected women attending the gynecology outpatient clinic. Chlamydia trachomatis was isolated from three (7.7%) of 39 postpartum women and eight (4.9%) of 162 women attending the gynecology clinic. The difficulties in storage and transportation of chlamydia specimens very likely led to an underestimate of the prevalence of chlamydia infection. No patient was found to be infected simultaneously with N. gonorrhoeae and C. trachomatis. Hence, 11.1% of postpartum women were infected with either N. gonorrhoeae or C. trachomatis.

A study now being conducted in Accra will provide current data on the prevalence of gonorrhea, chlamydia infection, trichomoniasis, and candidiasis. The study will include 150 male STD patients, 150 female STD patients, and 300 pregnant women. Of 131 pregnant women examined thus far, 15% had intracellular gram-negative diplococci in endocervical secretions (a finding strongly suggestive of gonorrhea), 2.3% had C. trachomatis antigen in endocervical secretions, 6% had Trichomonas vaginalis detected via wet smear microscopy, and 13% had Candida albicans detected via wet smear.

Available data indicate that gonorrhea and non-specific urethritis are the predominant STDs in Ghana, and that genital ulcer disease is uncommon in Accra and relatively more common in Kumasi. The public STD clinic in Adabraka (Accra) in 1992 recorded 51 cases of gonorrhea and non-specific urethritis, one of syphilis, and none of chancroid. In 1993, the clinic recorded 73 cases of gonorrhea and non-specific urethritis, none of syphilis, and none of chancroid. The public STD clinic at Komfo Anokye Teaching Hospital in Kumasi in 1992 recorded 165 cases of gonorrhea and non-specific urethritis, 28 cases of syphilis, and 42 cases of chancroid. These data also indicate that despite the probably large number of persons with STDs in Accra and Kumasi, relatively few are being seen in the public STD clinics in those cities.

The relatively small percentage of STD cases in Accra with syphilis might be due to a high prevalence of yaws among children. Immunity to Treponema pertenue, the causative agent of yaws, confers some protection against Treponema pallidum, the causative agent of syphilis. The possibly high prevalence of yaws also poses a problem with the use of

serologic tests to assess the prevalence of syphilis, as yaws can cause seroreactivity to the nontreponemal tests for syphilis, such as the VDRL and RPR tests

A population-based survey currently underway in the Eastern region is collecting data from 300 persons 15-49 years old on health-seeking behavior for STDs. These data should provide insights into the types of health-care providers from which patients seek care for STDs

Antibiotic-resistant N. gonorrhoeae is a major problem in Ghana. A study done at Komfo Anokye Teaching Hospital in Kumasi tested 356 isolates of N. gonorrhoeae for sensitivity to nine antibiotics, using disc diffusion methodology. The isolates were from the urethra (121 isolates), endocervix (96 isolates), high vaginal area (87 isolates), and conjunctiva (52 isolates). It is not known what percentage of the isolates were from patients who previously had been treated unsuccessfully with antibiotics. The percentage of isolates found susceptible to antibiotics were penicillin, 8%, tetracycline, 3%, co-trimoxazole (trimethoprim/sulfamethoxazole), 3%, chloramphenicol, 10%, erythromycin, 8%, spectinomycin, 78%, norfloxacin, 97%, cefuroxime, 95%, ceftriaxone, 100%. These results indicate that in Ghana the inexpensive antibiotics (penicillin, tetracycline, co-trimoxazole) are no longer effective in treating gonorrhea, and those antibiotics that are effective are expensive (norfloxacin, cefuroxime, ceftriaxone)

The finding that only a small percentage of N. gonorrhoeae isolates in Kumasi were sensitive to penicillin and tetracycline is consistent with results from other parts of sub-Saharan Africa. However, the finding that only 78% of isolates were sensitive to spectinomycin appears atypical. In Abidjan, Cote D'Ivoire, the percentage of isolates susceptible to antibiotics were penicillin, 30%, tetracycline, 43%, spectinomycin, 100%, ceftriaxone, 100%, and ciprofloxacin, 100%. In Dar es Salaam, Tanzania, the percentage susceptible were penicillin, 29%, tetracycline, 14%, spectinomycin, 93%, and ceftriaxone, 92%.

The heterogeneity of sexual behavior has a very important role in the epidemiology of STDs, in Ghana and elsewhere. A simple, useful characterization of heterogeneous sexual behavior is to assume there are two separate groups, a "core group" of highly sexually active persons and a "noncore group" which is much less sexually active.

A recent study by the World Bank estimated the benefits of preventing or curing a case of an STD in a person in the "core group" versus the "noncore group". The benefits are divided into static benefits and dynamic benefits. Static benefit is the benefit to only the cured or protected individual from curing or preventing a case of an STD. The dynamic benefit is the benefit due to the fact that, because of the communicability of the disease, each case of an STD prevented will prevent additional cases. Benefits are calculated as the number of healthy life years saved per case prevented or cured, taking into consideration ("discounting") the effect of the disease on productivity.

The World Bank study examined the benefits obtained under two different situations. The first was one in which STDs do not facilitate HIV transmission. The second was one in which STDs do facilitate HIV transmission.

Under the assumption that STDs do not facilitate HIV transmission, the analysis found that preventing or curing an STD case in a core-group person yielded four to eight times the total benefit as that obtained from preventing or curing a case in a noncore-group person (Table 1). Under the assumption that STDs do facilitate HIV transmission, the study found that there were nine to 15 times the benefit in preventing or curing an STD case in a core-group person vs a noncore-group person (Table 2). These results argue strongly that scarce STD-control resources (such as drugs) should be directed especially to persons in the core group.

Table 1 Discounted healthy life years saved per case prevented or cured when epidemics are independent core vs noncore

Disease	Static Benefit	Dynamic Benefit		Total Benefit	
		Core	Noncore	Core	Noncore
Chancroid	0.2	1.6	0.2	1.8	0.4
Chlamydia	1.1	43.0	4.4	44.1	5.5
Gonorrhoea	0.9	36.4	3.6	37.3	4.5
Syphilis	3.8	157.0	16.0	160.8	19.8

From: Over M and Piot P HIV infection and sexually transmitted diseases In Jamison DT, Mosley WH (editors), Disease Control Priorities in Developing Countries New York Oxford University Press for the World Bank

Table 2. Discounted healthy life years saved per case prevented or cured when STDs affect HIV transmission core vs noncore

Disease	Static plus Dynamic Benefit from STD only		Dynamic Benefit from averting HIV transmission		Total Benefit	
	Core	Noncore	Core	Noncore	Core	Noncore
Chancroid	1.8	0.4	53.8	3.4	55.6	3.8
Chlamydia	44.1	5.5	69.4	5.9	113.5	11.4
Gonorrhoea	37.3	4.5	82.9	7.1	120.2	11.6
Syphilis	160.8	19.8	235.5	21.3	396.3	41.1

From Over M. and Piot P HIV infection and sexually transmitted diseases In Jamison DT, Mosley WH (editors), Disease Control Priorities in Developing Countries New York Oxford University Press for the World Bank

## **2. Current Treatment of STDs in Ghana**

### **2.1 Results of study of STD treatment at six urban health centers**

A 1992 study of STD treatment at six urban health centers in Accra and four in Kumasi found that in both males and females, no physical examinations were done. All examination tables were of the flat type, with no facilities for examination in the lithotomy position. No vaginal specula were available.

At these facilities, health-care providers diagnosed all cases of urethral discharge as gonorrhoea, and few were aware of non-gonococcal urethritis. Seventy percent of providers prescribed antibiotics at the first visit, without waiting for the results of a gram stain, culture, and sensitivity they might have ordered. Treatment of gonorrhoea varied, with antibiotics used including cefuroxime, spectinomycin, amoxicillin, tetracycline, gentamicin, and co-trimoxazole.

Patients with vaginal discharge usually were treated with nystatin and metronidazole. Patients with vaginal discharge and lower abdominal pain were treated with nystatin, metronidazole, and tetracycline.

Less than 10% of providers gave patients any health education about STDs. Educational materials were not available, and health talks on STDs were not given in the outpatient departments. Only 25% of health-care providers advised patients with STDs to notify their partners to seek medical care. In general, providers thought it was more common for women to bring their partners. Only 40% of providers asked patients to return for follow-up care. These providers estimated that 90% of persons advised to return did not do so.

Laboratory tests for STDs were done only occasionally. All laboratories had at least one laboratory technician and one functioning microscope. Microscope slides and reagents for gram stains usually were not available. Serological tests for syphilis were not done at any of the laboratories. Information on laboratory tests performed was not readily available in any of the laboratories.

### **2.2 Guidelines of the National AIDS Control Programme for the treatment of STDs**

In March 1993, the National AIDS Control Programme of the Ministry of Health (MOH) developed guidelines for the management of STDs. These guidelines use algorithms for the treatment of urethral discharge, vaginal discharge, genital ulcers, and lower abdominal pain, the algorithms are similar to those developed by WHO for the syndromic approach to treating STDs. Importantly, however, these National AIDS Control Programme guidelines

recommend using tetracycline or doxycycline to treat gonorrhoea and chlamydia, regimens not likely to be effective for gonorrhoea due to tetracycline- and doxycycline-resistant N. gonorrhoeae. The guidelines also do not recommend alternative drugs for treating pregnant women, who should not be given tetracycline or doxycycline.

The guidelines also recommend treating candidiasis with nystatin or miconazole, which appear to be less preferable drugs to use than clotrimazole. Clinicians in Accra state that because nystatin must be used once daily for 14 days, patient compliance with this regimen is very poor. Miconazole is an extremely expensive drug. In addition, the guidelines for miconazole recommend using one 100-mg ovule intravaginally once daily for 7 days, which differs from the WHO-recommended miconazole regimen of 200 mg intravaginally once daily for 3 days. Also, a survey of 16 retail pharmacies in Accra found that they stocked miconazole ovules only in packs of three 400-mg ovules. Finally, the Essential Drug List and National Formulary includes only miconazole 500 mg/ovule.

Clotrimazole appears to be a better drug than nystatin or miconazole for treating candidiasis. A regimen using generic clotrimazole costs about the same as one using nystatin and much less than one using miconazole. In addition, a clotrimazole regimen is relatively convenient to use, with clotrimazole 200 mg inserted in the vagina once daily for three days.

### 2.3 Other information on current STD treatment

In September 1993, 13 medical officers from throughout Ghana participated in a Training of Trainers Workshop on the Management of STDs. Discussions held on the treatment of urethral discharge indicated that most physicians used spectinomycin as their first-choice drug, with norfloxacin and amoxicillin also being used successfully. Penicillin was reported to still be effective in some areas. In Volta Region, in-patients treated with tetracycline reportedly did not respond well to treatment.

### 2.4 STD treatment guidelines in the draft of the revised Essential Drug List and National Formulary

See section 4.2 for a discussion of these guidelines and the problems with them.

### 3. Syndromic Approach to Treating STDs

The World Health Organization (WHO) has recommended that health-care providers in developing countries treat patients with STDs on the basis of the group of symptoms, or syndrome, that the patient has, rather than for specific STDs. For example, providers would treat for vaginal discharge or a genital ulcer rather than gonorrhea or syphilis. Since several STDs can cause a particular syndrome, providers may need to treat for several STDs at the same time. For example, urethritis in men is a symptom of both gonorrhea and chlamydia infection. Therefore, providers using the syndromic approach in areas where both are prevalent should treat patients with urethritis for both STDs. Similarly, vaginal discharge is a symptom of bacterial vaginosis, candidiasis, chlamydia, gonorrhea, and trichomoniasis, and providers may need to treat patients for all five diseases. Information about the patient's sexual history can help to distinguish between syndromes that are sexually transmitted and other reproductive tract infections (especially candidiasis and bacterial vaginosis) which are not, or not usually sexually transmitted.

Syndromic diagnosis has several important benefits

- o It allows for appropriate treatment of symptomatic patients in one visit
- o It improves clinical diagnosis by avoiding wrong diagnoses and ineffective treatment
- o It can be learned by primary health care workers, including nurses, nurse-midwives, pharmacists, and chemical sellers

The main disadvantages of the syndromic approach are

- o Failure to adequately care for people with STDs who have no symptoms. Women with STDs often are asymptomatic
- o Wasting drugs on treatment for STDs that patients do not actually have

WHO does not recommend a two-tier drug policy, in which less effective drugs are provided at the peripheral health-care level and the most effective, and usually more expensive, drugs only at a referral level. Such a policy may result in an unacceptable rate of treatment failures, complications, and referrals, and may erode confidence in health services. The drugs used for STD in all health-care facilities should be at least 95% effective. The appropriate treatment of STD patients at their first encounter with a health provider is an important public health measure, since it is likely to reduce transmission of these diseases.

WHO has made the following drug recommendations for the treatment of STD-associated syndromes

Genital Ulcer Therapy for syphilis plus therapy for chancroid

Urethral Discharge Therapy for gonorrhea plus therapy for chlamydia

**Vaginal Discharge** An assessment of the patient's risk for an STD is made in order to guide treatment. The risk assessment is positive if the patient answers "Yes" to "Does your sexual partner have a discharge from his penis or open sores anywhere in his genital area?" The risk assessment also is positive if the patient has two or more of the following characteristics: under 21 years old, unmarried or not in union, with her husband or sexual partner for less than three months, had more than one sexual partner in the last four weeks.

If the risk assessment is negative: Therapy for candidiasis plus trichomoniasis plus bacterial vaginosis.

If the risk assessment is positive: Therapy for gonorrhoea plus chlamydia plus candidiasis plus trichomoniasis plus bacterial vaginosis.

**Lower Abdominal Pain in Women** An immediate referral to a hospital is made if the patient has a missed or overdue period, is pregnant, had a recent childbirth or abortion, has rebound tenderness or guarding, has vaginal bleeding, or has a pelvic mass. If these are not present, but the patient has a temperature of 38 C or higher, has pain during examination (on moving the cervix), or has a vaginal discharge, then she is treated for pelvic inflammatory disease. For patients with an intrauterine device (IUD), the IUD is removed 2-4 days after starting treatment. If the patient is well enough to take food and liquids, walk unassisted, take her medication, and return for follow-up, then outpatient treatment is begun. Otherwise, she is referred to a hospital. Outpatient therapy is for gonorrhoea (preferably a single-dose regimen) plus chlamydia plus anaerobic infections.

The drugs recommended by WHO for the therapy of specific STDs is as follows:

### Syphilis

Benzathine penicillin G, 2.4 million U in two intramuscular injections during one clinic visit, one injection is given in each buttock.

OR

Aqueous procaine penicillin G, 1.2 million U intramuscular injection daily for 10 days.

For men and nonpregnant women allergic to penicillin:

Doxycycline, 100 mg by mouth two times daily for 15 days.

OR

Tetracycline, 500 mg by mouth four times daily for 15 days.

For pregnant women allergic to penicillin:

Erythromycin, 500 mg by mouth four times daily for 15 days.

### Chancroid

Erythromycin, 500 mg by mouth three times daily for seven days

Alternative treatments are the following

Ciprofloxacin, 500 mg by mouth as a single dose (Do not give to pregnant women)

OR

Ceftriaxone, 250 mg intramuscular injection as a single dose (Single-dose regimens may not be effective in patients with HIV infection Preferred treatments are erythromycin or trimethoprim/sulfamethoxazole)

OR

Co-trimoxazole (trimethoprim, 80 mg/sulfamethoxazole, 400 mg), two tablets two times daily for seven days (Use only in areas where it has been proved effective against chancroid and where its effectiveness can be regularly monitored)

### Gonorrhoea

Cefixime, 400 mg by mouth as a single dose

OR

Ceftriaxone, 250 mg intramuscular injection as a single dose

OR

Ciprofloxacin, 500 mg by mouth as a single dose (Do not give to pregnant women)

OR

Spectinomycin, 2 grams intramuscular injection as a single dose

Alternative treatments are as follows

Kanamycin, 2 grams intramuscular injection as a single dose

OR

Co-trimoxazole (trimethoprim, 80 mg/sulfamethoxazole, 400 mg), 10 tablets once daily for three days (Use only in areas where it has been proved effective against gonorrhoea and where its effectiveness can be regularly monitored )

### Chlamydia

Doxycycline, 100 mg by mouth two times daily for seven days (Do not give to pregnant women)

OR

Tetracycline, 500 mg by mouth four times daily for seven days (Do not give to pregnant women)

Alternative treatments are as follows

Erythromycin, 500 mg by mouth four times daily for seven days

OR

Sulfisoxazole, 500 mg by mouth four times daily for 10 days

**Candidiasis**

Miconazole or clotrimazole, 200 mg inserted in the vagina once daily for three days

OR

Nystatin, 100,000 U inserted in the vagina once daily for 14 days

OR

Clotrimazole, 500 mg inserted in the vagina as a single dose

**Trichomoniasis and Bacterial Vaginosis**

Metronidazole, 2 grams by mouth as a single dose

OR

Metronidazole, 400-500 mg by mouth two times daily for seven days

Do not give metronidazole to women in the first three months of pregnancy (Delay any treatment until the fourth month of pregnancy)

**Anaerobic Infections in Pelvic Inflammatory Disease**

Metronidazole, 400-500 mg by mouth two times daily for 10 days

#### 4. Status of Ghana's Essential Drug List and National Formulary

##### 4.1 Drugs for STDs now in the Essential Drug List and National Formulary

The following drugs are in Ghana's Essential Drug List and National Formulary and also are mentioned in the WHO-recommended STD-treatment regimens, described above

Benzathine benzylpenicillin G, for injection, 2.4 million U per vial

Aqueous procaine penicillin G, for injection, 1 million U per vial and 4 million U per vial

Erythromycin, 250 mg/tablet

Metronidazole, 200 mg/tablet

Miconazole, 500 mg/vaginal ovule

Tetracycline, 250 mg/capsule

Trimethoprim/sulfamethoxazole, each tablet contains 80 mg trimethoprim and 400 mg sulfamethoxazole

Several problems exist with the composition of Essential Drug List and National Formulary

First, none of the drugs on the list remain adequately effective in treating gonorrhea in Ghana

Second, poor patient compliance should be expected with regimens that use tetracycline to treat chlamydia or to treat syphilis in men and nonpregnant women allergic to penicillin. These regimens require patients to take two 250-mg tetracycline capsules four times daily for seven days (for chlamydia) or 15 days (for syphilis). By contrast, regimens that use doxycycline to treat chlamydia or syphilis require patients to take one 100-mg doxycycline capsule two times daily for seven days and 15 days, respectively. If the drugs are purchased via UNICEF, the doxycycline-containing regimens are less expensive. However, if drugs are purchased from retail pharmacies, the doxycycline-containing regimens are more expensive.

Third, miconazole is a very expensive drug with which to treat candidiasis. Less expensive, effective drugs are available. The regimen that uses clotrimazole 200 mg inserted in the vagina once daily for three days is far less expensive than a miconazole-containing regimen. Another inexpensive treatment for candidiasis is nystatin 100,000 U inserted in the vagina once daily for 14 days. However, the need to use nystatin for 14 days results in such poor compliance that one STD physician in Accra described nystatin as "useless" for candidiasis.

#### 4.2 Problems with the draft of the revised Essential Drug List and National Formulary

The Essential Drug List and National Formulary contains a listing of the drugs on the Essential Drug List, information about each of the drugs, and guidance on how certain medical conditions should be treated. Because of the shortage of commercially published drug information in most developing countries (including Ghana), a national formulary manual is vital to provide information on the proper use of drugs included on the national formulary list. If the manual exists but has not been revised within five years, it may not reflect current information on the drugs listed (and may have no information on drugs which have been added to the formulary list).

The last time the Essential Drug List and National Formulary was published was 1988. In 1990, the list of drugs was revised but not published. In late 1991, a draft of a revised Essential Drug List and National Formulary was submitted to the MOH. This revision included current 1991 information about each of the drugs on the 1990 list. The MOH took no action on this draft. In late 1993, another revision of the Essential Drug List and National Formulary was submitted to the MOH. This revision included current 1993 information about each of the drugs on the 1990 list. This revision is supposed to be printed shortly, using funds from UNICEF.

The revision of the Essential Drug List and National Formulary that is due to be printed has a two-page section on the treatment of STDs. This STD section contains recommendations on the treatment of urethral discharge in men and vaginal discharge. However, there are several problems with its recommendations.

First, the STD section recommends that urethral discharge be treated with penicillin or amoxicillin. These antibiotics are very unlikely to be effective, due to antibiotic-resistant gonorrhoea. The reason that the section cannot recommend effective antibiotics is that any drugs recommended in the Essential Drug List and National Formulary must already be on the Essential Drug List, and the Essential Drug List contains no drugs still effective for treating gonorrhoea in Ghana.

Second, the STD section recommends that patients with urethral discharge be treated first for gonorrhoea. If seven days later the discharge is still present, then the patient is treated for chlamydia, using tetracycline. This approach will require all patients with chlamydia to make a second visit to the health facility. However, many patients will not return for a second visit. The WHO recommends that effective treatment for STD syndromes be provided in the first visit, and that in areas (such as Ghana) where both gonorrhoea and chlamydia are common, patients with urethral discharge be treated for both illnesses at the first encounter.

Third, the STD section does not use a syndromic approach to the treatment of vaginal

discharge. Rather, it recommends that treatment of vaginal discharge be based on the appearance of the discharge. However, a study done in health facilities in Accra and Kumasi found that in both male and female STD patients no physical examinations were done, all examination couches were of the flat type with no facilities for lithotomy examination, and that vaginal specula were absent. Hence, the health-care provider will not be able to visualize the vaginal discharge. Given this situation, the treatment of vaginal discharge should use the syndromic approach, described previously in this report.

Fourth, the STD section is not consistent with the guidelines for the management of STDs that have been developed by the National AIDS Control Programme of the MOH. These guidelines use algorithms for the treatment of urethral discharge, vaginal discharge, genital ulcers, and lower abdominal pain, the algorithms are similar to those developed by WHO for the syndromic approach to treating STDs. (It should be noted, however, that these National AIDS Control Programme guidelines recommend using tetracycline to treat gonorrhoea, a regimen not likely to be effective due to tetracycline-resistant gonorrhoea. In addition, the guidelines do not recommend an alternative treatment for gonorrhoea in pregnant women, who should not be given tetracycline.)

Given the limitations of the STD section in the proposed revision of the Essential Drug List and National Formulary, it is recommended that printing of the revision be delayed until additional drugs effective in treating STDs are added to the list (see section 5 below) and the STD section is revised. If printing cannot be delayed, or other factors make such a delay undesirable, it is recommended that the section on the treatment of STDs not be included in the revision.

#### 4.3 The impact on treatment guidelines of adding a drug to the Essential Drug List and National Formulary

In developing treatment guidelines, the MOH can recommend only drugs that are in the Essential Drug List and National Formulary. This is the case even if the Essential Drug List and National Formulary includes no drugs effective in treating a particular illness. For example, in developing guidelines for the treatment of gonorrhoea, the National AIDS Control Programme has not been able to officially recommend any drugs adequately effective for gonorrhoea. As described above, the same limitation applies to the recommendations for the treatment of gonorrhoea made in the STD section of the Essential Drug List and National Formulary.

Hence, a major impact of adding drugs effective for STDs to the Essential Drug List and National Formulary is that the MOH will be able to develop STD treatment guidelines recommending drugs more effective than those now in the national formulary.

#### 4.4 The impact on drug supplies at health facilities of adding a drug to the Essential Drug List and National Formulary

Separate revolving (Cash and Carry) funds are maintained by the MOH (for the Central Medical Store), by each regional administration (for regional medical stores), and by each health facility. The Central Medical Store purchases only drugs listed in the Essential Drug List and National Formulary. Regional medical stores are supposed to purchase drugs only from the Central Medical Store, but in fact purchase drugs also from the private sector. Health facilities are supposed to purchase drugs only from the Central Medical Store and regional medical stores, but they also purchase drugs directly from private sector. Some of the drugs purchased from the private sector by the regional medical stores and health facilities are not in the Essential Drug List and National Formulary.

Each region and facility has control of its own fund and can set its own pricing procedures. In reality, each facility can be considered a separate non-profit business, and therefore, needs to operate on a businesslike basis in order to survive.

Adding a drug to the Essential Drug List and National Formulary will enable the MOH to use the revolving fund of the Central Medical Store to purchase the drug, via the Ghana Supply Commission. Because the MOH often purchases large quantities of a drug, it might be able to obtain the drug for a low price, one possibly lower than what private wholesale drug suppliers would have to pay. Hence, adding a drug to the Essential Drug List and National Formulary enables the drug to be purchased at low price by the MOH, which can then sell the drug, via the Central Medical Store, to the regional medical stores and health facilities. The lower price available through large purchases can thereby be passed along to the patient.

As noted above, adding a drug to the Essential Drug List and National Formulary will enable the MOH to recommend the drug in its treatment guidelines. This will increase use of the drug by health-care providers, who will request that the health facility stock and sell the drug via its Cash and Carry Programme. In addition, patients unable to purchase the drug at the health facility will go to pharmacists to buy the drug, the pharmacists in turn will begin to stock the drug as they see that demand for it has increased. Hence, adding a drug to the Essential Drug List and National Formulary will result in the drug being more widely available.

## 5. Recommendations for Drugs to be Added to the Essential Drug List and National Formulary

It is recommended that the following drugs and dosage forms be added to the Essential Drug List and National Formulary

- Ciprofloxacin 500 mg/tablet
- Ceftriaxone 250 mg/vial
- Doxycycline 100 mg/tablet or capsule
- Clotrimazole 100 mg/vaginal tablet

For each drug, the reasons underlying this recommendation are discussed below

### Ciprofloxacin

In Ghana, a large percentage of N. gonorrhoeae isolates are resistant to penicillin, tetracycline, and co-trimoxazole. This requires that additional drugs, effective in treating gonorrhea, be added to the Essential Drug List and National Formulary. Drugs for treating gonorrhea ideally should have the following characteristics:

- High efficacy
- Low cost
- Acceptable toxicity and tolerance
- Organism resistance is either unlikely to develop or will be delayed
- Single dose
- Oral administration
- Not contraindicated for pregnant women or lactating women

No drug has all of these characteristics. Ciprofloxacin has the following advantages:

- High efficacy
- Low cost: according to a price quote from the UNICEF Supply Division in Copenhagen, ciprofloxacin 500 mg/tablet now costs only \$0.40/tablet when purchased in packs of 500 tablets
- Acceptable toxicity and tolerance
- Organism resistance is either unlikely to develop or will be delayed
- Single dose: one 500 mg tablet
- Oral administration

Given that ciprofloxacin 500 mg/tablet now costs only \$0.40/tablet when purchased in packs of 500 tablets, in the international market ciprofloxacin is by far the least expensive of the first-line drugs recommended by WHO for the treatment of gonorrhea, the other first-line drugs are cefixime, ceftriaxone, and spectinomycin (Table A.5).

A disadvantage of ciprofloxacin is that it should not be given to pregnant women because it caused permanent lesions of the cartilage of weight-bearing joints in immature animals of

most species tested. Related drugs, such as norfloxacin, also produced these lesions and should not be given to pregnant women.

Currently in Ghana, ciprofloxacin is not widely available. A survey of 16 pharmacies in Accra found only two that stocked the drug. By contrast, norfloxacin (a drug related in chemical structure to ciprofloxacin and effective in treating gonorrhea) was available in all 16 of the pharmacies. Pharmacists said that they would stock ciprofloxacin if doctors began to prescribe it more frequently. Doctors very likely would prescribe ciprofloxacin more often if it were included in the Essential Drug List and National Formulary and health-care providers were trained to use it as the first-choice drug for gonorrhea.

Ciprofloxacin has several advantages over norfloxacin in treating gonorrhea. One advantage is that to treat gonorrhea requires taking only one 500-mg ciprofloxacin tablet vs. two 400-mg norfloxacin tablets taken at the same time. The ciprofloxacin one-tablet regimen probably will lead to fewer dosing errors than the norfloxacin two-tablet regimen. Patients taking norfloxacin might misunderstand the dosing instructions and take the two norfloxacin tablets at different times, thus leading to marginal or inadequate serum concentrations of the antibiotic. Also, because norfloxacin is relatively expensive (as is ciprofloxacin in retail pharmacies), patients might buy only one norfloxacin tablet and see if that is effective. The potential for underdosing with norfloxacin might speed the development of norfloxacin-resistant gonorrhea.

A second advantage of ciprofloxacin is that in vitro ciprofloxacin 500 mg is 10 to 20 times more active against N. gonorrhoeae than norfloxacin 800 mg. (For details, see Table 3.) Ciprofloxacin's greater activity against N. gonorrhoeae will delay the development of antibiotic resistance. Norfloxacin has less therapeutic reserve, and therefore antibiotic resistance is more likely to develop to it. Indeed, in Rwanda N. gonorrhoeae became much less susceptible to norfloxacin during a four-year period, despite the drug being available at only one health facility in the country. Norfloxacin's smaller therapeutic reserve and wide availability in Accra suggest that norfloxacin-resistant gonorrhea might soon be a problem in Ghana.

### Ceftriaxone

Ceftriaxone is recommended for addition to the Essential Drug List and National Formulary for use in the treatment of gonorrhea in pregnant women, disseminated gonococcal infection, inpatient therapy of pelvic inflammatory disease, and gonococcal ophthalmia in neonates. Ceftriaxone is administered by intramuscular injection or intravenously. These are the routes by which treatment must be given for disseminated gonococcal infection, inpatient therapy of pelvic inflammatory disease, and gonococcal ophthalmia. It is vitally important to have on the Essential Drug List and National Formulary a drug effective against N. gonorrhoeae that is given intramuscularly or intravenously, so that these very serious illnesses can be treated.

Table 3 Pharmacokinetics of ciprofloxacin and norfloxacin in relation to the minimum inhibitory concentration of Neisseria gonorrhoeae

Characteristic	Ciprofloxacin		Norfloxacin	
	250 mg	500 mg	400 mg	800 mg
Maximum serum concentration (mcg/ml)	1.20	2.40	1.50	2.40
Half-life (hours)	4.00	4.00	3.50	3.50
Serum concentration at 10 hrs (mcg/ml)	0.21	0.42	0.21	0.33
MIC90 (mcg/ml) <sup>a</sup>	0.008	0.008	0.06 or 0.125 <sup>b</sup>	0.06 or 0.125
Serum concentration at 10 hrs/MIC90	26.5	53.0	3.5 or 1.7	5.5 or 2.6

<sup>a</sup> MIC90 = minimum inhibitory concentration at which there is no visible growth of 90% of isolates

<sup>b</sup> In two different studies, the MIC90 for norfloxacin was 0.06 and 0.125, the MIC90 in the larger study was 0.125. In both studies, the MIC90 for ciprofloxacin was 0.008.

**Explanatory note** The activity of an antibiotic against an isolate of N. gonorrhoeae is assessed by measuring the minimum inhibitory concentration (MIC), which is the lowest concentration of antibiotic allowing no visible growth of that isolate. The MIC90 is the concentration allowing no visible growth of 90% of isolates tested. In treating gonorrhoea, you want to have serum concentrations three to four times the MIC of the infecting N. gonorrhoeae sustained for seven to 10 hours. In this table, the last line presents the ratio of the MIC90 to the serum concentration at 10 hours. This shows that ciprofloxacin 500 mg is 10 to 20 times more active against N. gonorrhoeae than norfloxacin 800 mg.

The only other drug that might be considered for these illnesses is spectinomycin, but data from Kumasi indicate that 22% of N. gonorrhoeae isolates are spectinomycin-resistant

### Doxycycline

Doxycycline is effective in the treatment of chlamydia in non-pregnant women, and of syphilis in men and non-pregnant women allergic to penicillin. With good patient compliance, these illnesses can be treated with tetracycline, which already is in the Essential Drug and National Formulary. However, health-care providers experienced in treating STDs state that few patients are able to comply with regimens that use tetracycline for chlamydia or syphilis. These regimens require patients to take two 250-mg tetracycline capsules four times daily for seven days (for chlamydia) or 15 days (for syphilis). By contrast, regimens that use doxycycline to treat chlamydia or syphilis require patients to take one 100-mg doxycycline capsule two times daily for seven days and 15 days, respectively.

If the drugs are purchased via UNICEF, the doxycycline-containing regimens are less expensive (Tables A 5 and A 6). However, if drugs are purchased from retail pharmacies, the doxycycline-containing regimens are more expensive (Tables A 2 and A 3).

### Clotrimazole

Clotrimazole is an inexpensive and effective treatment for candidiasis. The recommended treatment regimen is generic clotrimazole (100 mg/vaginal tablet) 2 tablets inserted in the vagina once daily for three days. The alternative drugs for candidiasis are miconazole and nystatin. Miconazole, which is in the current Essential Drug List and National Formulary, is very expensive. Nystatin must be used for 14 days, resulting in poor patient compliance. Indeed, one clinician in Accra who treats many STD patients stated that because of poor compliance, nystatin was "useless" for treating candidiasis.

In the international market, clotrimazole- and nystatin-containing regimens are the same price (Table A 5 in the Appendix). In retail pharmacies in Accra, generic clotrimazole-containing regimens are slightly more expensive (Table A 2). In both settings, miconazole-containing regimens are far more expensive than the other regimens.

## 6. Cost of drugs for treating STDs in Ghana

### 6.1 Retail pharmacy price of drugs for STDs

To determine the retail cost in Ghana of drugs that are used in treating STDs, 16 retail pharmacies in Accra were visited and data were collected on drug prices. The 16 pharmacies were located throughout Accra. No formal sampling scheme was used.

The retail pharmacy prices are presented in Table A 1 in the Appendix. These prices were used to calculate the cost of the syndromic treatment of urethral discharge, vaginal discharge, genital ulcers, and lower abdominal pain (Tables A 2 and A 3).

### 6.2 Wholesale international-market price of drugs for STDs

To determine the cost to the Government of Ghana in the international market for drugs used in treating STDs, a variety of sources were used. The estimated prices are presented in Table A 4. These prices were used to calculate the cost of the syndromic treatment of urethral discharge, vaginal discharge, genital ulcers, and lower abdominal pain (Tables A 5 and A 6).

### 6.3 Drug costs for syndromic treatment of STDs: retail pharmacy prices vs wholesale international-market prices

Table A 7 presents the costs for syndromic treatment of STDs using the drugs recommended for addition to the Essential Drug List and National Formulary, based on cost of these drugs in the wholesale international market vs retail pharmacies in Accra. The costs are summarized in Table 4 below.

As shown Table 4, the retail pharmacy prices for drugs used in the syndromic treatment of STDs are 2.4 to 8.9 times the wholesale international-market prices.

Of note is that the retail pharmacy prices for ciprofloxacin and doxycycline are 5.8 and 15.1 times, respectively, the wholesale international-market prices (Table A 7). The price advantage of the international market for these drugs reflects the very low prices for ciprofloxacin and doxycycline when they are purchased through UNICEF.

Table 4. Costs for syndromic treatment of sexually-transmitted diseases using drugs recommended for addition to the Essential Drug List and National Formulary, based on cost of drugs in the international market vs. retail pharmacies in Accra.<sup>a</sup>

Syndrome	Wholesale International Drug Price (in US \$)	Retail Pharmacy Drug Price (in US \$)
Urethral Discharge	0 60	5 31
Vaginal Discharge		
Cervicitis and vaginitis <sup>b</sup>	1 36	7 70
Vaginitis only <sup>c</sup>	0 76	2 39
Genital Ulcer	2.01	4 91 <sup>d</sup>
Lower Abdominal Pain	1.05	6 28

<sup>a</sup> Wholesale international-markets prices are drawn from several listings and are approximate. Retail pharmacy prices are based on the median price found in a survey of 16 retail pharmacies in Accra.

<sup>b</sup> Treatment for vaginitis and cervicitis includes treatment for gonorrhoea, chlamydia, trichomoniasis, bacterial vaginosis, and candidiasis

<sup>c</sup> Treatment for vaginitis includes treatment for trichomoniasis, bacterial vaginosis, and candidiasis

<sup>d</sup> Benzathine penicillin 2.4 million U/vial was not available in the pharmacies surveyed. For purposes of comparison, the wholesale international-market price is used for the retail pharmacy price.

#### 6.4 Price the Cash and Carry Programme needs to charge patients for drugs purchased on the international market

The Cash and Carry Programme at health facilities will not be able to sell drugs to patients at the wholesale international-market price. This is because the Cash and Carry Programme must sustain revolving drug funds at each medical store and each health facility. The goal is to recover, at each level of the system, the full costs of repurchasing the same quantity of drugs that were sold. Since the nationwide implementation of Cash and Carry, no supplementary funds have been provided from the recurrent budget for drug purchases, so Cash and Carry revenue must be adequate to cover re-purchase costs for all drugs.

The price the patient is charged will reflect expenses incurred at each level of the supply system. This system includes the Central Medical Store, regional medical stores, and health facilities. Additional costs that should be considered when setting drug prices include

- o The cost of drugs issued free to exempt patients and staff
- o Losses from drugs issued to patients or facilities which do not pay
- o Wastage due to expiry

Other costs that may be incorporated into the sales price include

- o Transport costs for delivering or collecting drugs
- o Salary and other operating costs

The overall markup or margin at each level of the system must be such that the average sales price of all drugs in stock equals the average next purchase cost for all of those drugs. If this is not achieved, the fund will decapitalize, unless the government provides budget support to make up the shortfall.

Taking into account these factors, an analysis by the Rational Pharmaceutical Management Project of Ghana's pharmaceutical sector estimated what health facilities need to charge patients for drugs. For local drug purchases, the analysis estimated that health facilities need to charge patients 1.5 to 1.9 times the price paid by the MOH. For international drug purchases, patients would need to be charged 2.5 to 3.1 times the price paid by the MOH.

## 7. STD-related activities of other donor organizations

### 7.1 Commission of the European Community

During 1994, the Commission of the European Community is funding several STD activities. A study is being done in Eastern Region to assess the quality of STD care provided in public and private health facilities. The study will determine (1) whether patients presenting with symptoms of an STD receive appropriate clinical care, (2) the proportion of patients with STD symptoms given appropriate advice on condom use and partner notification, and (3) what barriers impede the delivery of appropriate case management in health facilities and how those barriers can be removed.

A second study will examine the health-seeking behavior of a representative sample of 300 persons 15-49 years old in the Eastern Region. The study will determine the (1) awareness of STDs, (2) prevalence of STD symptoms, (3) health care sought for STD symptoms, and (4) barriers to seeking care for STD symptoms.

A third study is being conducted in Accra among 300 pregnant women and 300 patients presenting with urethral discharge, dysuria, vaginal discharge, lower abdominal pain, or genital ulcers. The study is determining the (1) prevalence of STD syndromes, (2) pathogens causing STD syndromes, and (3) antibiotic sensitivity of N gonorrhoeae. Specimens will be collected for wet mount, gram stain, culture and sensitivity of N gonorrhoeae, Chlamydia ELISA, and serological tests.

The Commission also will fund (1) training in STDs for medical officers, medical assistants, and nurses, (2) reprinting of STD leaflets, (3) the development and printing of an STD poster and flipchart, (4) the preparation of a final draft and printing of national guidelines for STD case management, and (5) training in STDs for regional HIV/AIDS counsellors.

### 7.2 GTZ

GTZ supports laboratories in Wa (Upper West Region) and Tamale (Northern Region) to do serological tests, including HIV ELISA and Western blot tests, TPHA tests for syphilis, and hepatitis B antigen tests. In 1993, GTZ supplied the laboratory in Wa with equipment and reagents to culture N gonorrhoeae and do antibiotic sensitivity tests, using disk diffusion. A laboratory technologist in Wa received microbiology training in Kumasi at the laboratory of Dr. Y. Adu-Sarkodie, an STD specialist and microbiologist at Komfo Anokye Teaching Hospital. In addition, a medical officer from Wa was trained in Kumasi by Dr. Adu-Sarkodie in the clinical management of STDs.

Despite being fully equipped and staffed, the STD portion of the laboratory in Wa is not doing any STD-related work. This is because the person in charge of the overall Wa laboratory, who is the only formally trained microbiologist there, has a chronic, debilitating illness that seriously impairs his judgement and ability to manage and provide supervision. Consequently, he will not allow the technologist trained in STD-microbiology techniques to do the STD laboratory work.

GTZ will be funding Dr Adu-Sarkodie, who is in London for the year, to do an assessment of the laboratory in Wa. The goal is to have Dr Adu-Sarkodie get the laboratory in Wa performing STD-related work or to decide to re-locate the laboratory equipment and staff to Bolgatanga (Upper East Region).

### 7.3 Overseas Development Administration (British Aid)

The Overseas Development Administration (ODA) will support the establishment of STD clinics at the Regional Hospitals in Ho (Volta Region) and Koforidua (Eastern Region). Support will be in the form of medical equipment, consumable supplies, and laboratory reagents. These supplies will allow the STD clinics to collect specimens, perform culture and sensitivity testing for *N. gonorrhoeae*, and do the RPR and TPHA serologic tests for syphilis. ODA also is funding STD-specialist training in Great Britain for two physicians, who on their return will be in charge of the STD clinics in Ho and Koforidua. ODA also will be providing equipment and supplies for an STD clinic in Korle Bu Hospital (Accra).

ODA also is funding refresher training in STDs for private physicians and pharmacists in Accra/Tema and Kumasi. ODA has funded a Health Education Research Unit in Kumasi, which will be developing a poster encouraging individuals with STD symptoms to seek appropriate treatment. It also has funded the reproduction of educational materials about STDs.

### 7.4 Ghana-Denmark Health Sector Support Program

This newly established program will fund a regional health project in Upper West Region that is intended to improve health services for AIDS prevention, STD treatment, and family planning.

## 8. Other Recommendations on STD-Related Issues

8 1 Consideration should be given to funding, via the GHANAPA Project, meetings and certain other activities needed to enact changes in the Essential Drug List and National Formulary

To revise the Essential Drug List and National Formulary so that it includes the drugs recommended in this report, meetings need to be held with members of the Faculty of Pharmacy of the University of Science and Technology, Kumasi, which is the only Faculty of Pharmacy in Ghana. To have these meetings, members of the Faculty of Pharmacy will need to travel to Accra, thereby incurring expenses for travel, lodging, and meals. In addition, revising the Essential Drug List and National Formulary will incur expenses for drafting and editing of the revision. Consideration should be given to providing funds for these expenses.

8 2 Consideration should be given to establishing the following conditionality for Non-Project Assistance in the GHANAPA Project

After the Essential Drug List and National Formulary is revised to include the drugs recommended in this report, the National AIDS Control Programme will revise its STD-treatment guidelines so that the first-choice drug for (1) gonorrhea is ciprofloxacin, except among pregnant women, who should be treated with ceftriaxone, (2) chlamydia is doxycycline or tetracycline, except among pregnant women, who should be treated with erythromycin, (3) candidiasis is generic clotrimazole.

8 3 Consideration should be given to establishing the following conditionality for Non-Project Assistance in the GHANAPA Project

After the conditionality in 8 2 is fulfilled, the STD- treatment guidelines in the Essential Drug List and National Formulary will be revised so that they are identical to those of the National AIDS Control Programme, and the Essential Drug List and National Formulary will be printed and distributed to all health facilities.

8 4 Consideration should be given to funding activities to prevent and treat STDs among high-risk populations, including commercial sex workers and their clients. Currently, the MOH does not have any such outreach activities. The activities should include counselling, provision of condoms, and syndromic treatment of STDs, with free or subsidized drugs provided by senior nurses at the workplaces of the sex workers. By far, high-risk populations are the group among whom it is most cost-beneficial to prevent and treat STDs (See analysis on core groups in section 1).

#### 8.5 Consideration should be given to the following

- o Providing the Public Health Reference Laboratories in Accra and Kumasi with the equipment and supplies needed to do agar-dilution sensitivity testing of N. gonorrhoeae
- o Providing Noguchi Memorial Institute at the University of Ghana with certain accessories to its freeze-dryer that will facilitate preparation of freeze-dried N. gonorrhoeae specimens

This recommendation is made to improve laboratory surveillance of antibiotic-resistant gonorrhea, which is essential to maintaining effective treatment guidelines. There are two laboratory methods of testing for antibiotic sensitivity, disk-diffusion method and agar-dilution method. Disk-diffusion testing is easier to perform but is poorly standardized, since there are many variables associated with it, one problem being the availability of antibiotic discs of the correct content. For surveillance of antibiotic resistance, WHO recommends using the agar-dilution method.

Laboratory consultants and microbiologists in Ghana think that the Public Health Reference Laboratories in Accra and Kumasi, whose construction and equipment USAID funded, will have staff with the technical capability to do agar-dilution sensitivity testing. However, the laboratories will require certain supplies and equipment to do this testing, including antibiotic powders, Mueller-Hinton broth and agar, and a replicator. These can be provided at modest expense.

Drugs recommended for the treatment of gonorrhea should be at least 95% effective. If the Public Health Reference Laboratories find that greater than 5% of N. gonorrhoeae isolates are resistant to the antibiotics considered effective (ciprofloxacin, norfloxacin, ceftriaxone), the resistance of those isolates should be confirmed at reference laboratories, such as ones at the Centers for Disease Control or the Institute of Tropical Medicine (Antwerp). To be sent to the reference laboratories, the isolates need to be freeze-dried or shipped on dry ice. The Bacteriology Unit at Noguchi Memorial Institute at the University of Ghana is able and willing to freeze-dry the specimens. The preparation of the freeze-dried specimens would be facilitated if the laboratory was supplied with certain accessories to its freeze-dryer. These accessories are produced by Edwards High Vacuum, Inc. The brand name is Modulyo Range. The accessories are the following:

- o Spin freezer 96, 220 V model Model # F056-37-000
- o Secondary drying manifold Model # FO29-64-000
- o Additional secondary drying manifold # F029-56-000

The United States address of Edwards High Vacuum is 3279 Grand Island Boulevard, Grand Island, New York 14072 (Phone 800-828-6691, Fax 716-773-3864)

If the Public Health Reference Laboratories in Accra and Kumasi develop the capability to do agar-dilution testing, then N. gonorrhoeae isolates from laboratories in other regions of Ghana could be sent to them for testing, thus strengthening the surveillance system. Laboratories that might be able to participate in this system include those being equipped by ODA in Ho and Koforidua, and the GTZ-funded STD laboratory when it becomes operational. However, these laboratories would need to be supplied with refrigerators that could store N. gonorrhoeae isolates at -20 C, and must have a reliable source of electricity for the refrigerator. The possibility of including these laboratories in the surveillance system might be considered in the medium-term.

8.6 If USAID/Ghana decides that to improve surveillance for antibiotic-resistant N. gonorrhoeae, it will provide the Public Health Reference Laboratories in Accra and Kumasi with equipment and supplies needed for agar-dilution sensitivity testing, then consideration should be given to establishing the following conditionality:

The MOH will use the results of antibiotic-sensitivity testing done at the Public Health Reference Laboratories in Accra and Kumasi to evaluate whether its guidelines for the treatment of STDs should be changed.

8.7 Consideration should be given to funding operations research on the syndromic treatment of STDs, especially of vaginal discharge. Research should determine:

- o the validity of using risk assessment in the vaginal-discharge algorithm and how to improve risk assessment
- o the accuracy of the algorithm for lower abdominal pain
- o the quality of STD-case management
- o the percent of patients who buy drugs prescribed
- o the percent of patients whose partners are notified and seek treatment

Studies in other countries suggest that WHO-proposed algorithms using risk assessment in treating vaginal discharge might need to be modified according to the countries and places they are used. Studies should be carried out in Ghana with different groups of women: prenatal, postnatal, new patients, patients with long-time follow-up, and commercial sex

workers

8 8 Consideration should be given to conducting periodic surveys among well-defined groups to determine the incidence and prevalence of symptoms highly suggestive of STDs

There are very limited data on the incidence and prevalence of STDs in Ghana, particularly among men. To address this issue, one could conduct anonymous surveys by self-administered questionnaire of populations in certain institutions, such as the military or secondary school. To attempt to elicit honest responses about symptoms highly suggestive of STDs, individuals would be told not to put their names on the questionnaires and would be given envelopes in which to put the completed questionnaires.

The possibility of conducting such a survey among military personnel was discussed with Lt Colonel Frank Appeagyei, Head of Army Health Department of Military Hospital (Accra) and Head of Preventive Services, Ghana Armed Forces. Lt Colonel Appeagyei supported conducting such a survey, and suggested it might be done among the 1,000 Ghanaian soldiers sent every nine months to the United Nations Peacekeeping Force in Lebanon. These soldiers, drawn from Army outposts throughout Ghana, are examined at Military Hospital in Accra prior to being sent overseas. Lt Colonel Appeagyei said it would be feasible to have the soldiers complete an anonymous questionnaire about symptoms highly suggestive of STDs. In addition, the survey could be done every nine months, when a new group of soldiers is examined.

Another group among whom such anonymous surveys might be done are secondary-school students in the higher grades, a very sexually active population. A survey in this group could collect data not only on STD symptoms but also on sexual activity, awareness of HIV transmission, and contraceptive practice.

## **PERSONS MET**

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**Appendix**  
**(Tables A 1 to A 7)**

Table A 1. Retail pharmacy prices in Accra of antibiotics used to treat sexually-transmitted diseases <sup>a</sup>

Drug	Dosage form	Number of pharmacies selling drug in dosage form	Price (in Cedi)		Price (in US dollars)	
			Median	Range	Median	Range
Benzathine penicillin	2.4 million vial	0	NA <sup>b</sup>	NA	NA	NA
Cefixime	400 mg tablet	0	NA	NA	NA	NA
Ceftriaxone	250 mg vial	0	NA	NA	NA	NA
Ciprofloxacin	500 mg tablet	2	2150	1800-2500	2.31	1.94-2.69
Clotrimazole	pack of 6					
Generic	100 mg vaginal tablets	7	2000	1600-3000	2.15	1.72-3.23
Brand-name	100 mg vaginal tablets	12	8000	4500-9350	8.60	4.84-10.05
Co-trimoxazole	80 mg trimethoprim/400 mg sulfamethoxazole tablet	16	30	20-50	0.03	0.02-0.05
Doxycycline	100 mg capsule	11	200	100-500	0.22	0.11-0.54
Erythromycin	250 mg tablet	15	100	75-250	0.11	0.08-0.27
Kanamycin	1 or 2 g vial	0	NA	NA	NA	NA
Metronidazole	200 mg tablet	16	22.5	15-40	0.02	0.02-0.04
Miconazole	pack of 3					
	400 mg vaginal ovules	11	7300	4500-7800	7.85	4.84-8.39
Norfloxacin	400 mg tablet	16	1550	1000-2000	1.67	1.08-2.15
Nystatin	pack of 12, 14, or 15					
	100,000 IU vaginal tablets	16	1650	1400-2500	1.77	1.51-2.69
Spectinomycin	2 g vial	13	9000	6500-9500	9.68	6.99-10.22
Tetracycline	250 mg capsule	16	27.5	20-40	0.03	0.02-0.04

<sup>a</sup> Sixteen retail pharmacies were included in the survey

<sup>b</sup> NA=not available in pharmacies surveyed.

Table A 2 Costs for syndromic treatment of urethral discharge and vaginal discharge, based on cost of drugs in retail pharmacies in Accra \*

Syndrome	Drug choices	Course of treatment	Cost (in Cedi)	Cost (in US \$)
<u>Urethral Discharge</u>				
For gonorrhoea	Cefixime	400 mg as a single dose	NA <sup>b</sup>	NA
	Ceftriaxone	250 mg IM as a single dose	NA	NA
	Ciprofloxacin	500 mg by mouth as a single dose	2,150	2.31
	Norfloxacin	800 mg as a single dose	3,100	3.33
	Spectinomycin	2 g IM as a single dose	9,000	9.68
	Kanamycin	2 g IM as a single dose	NA	NA
	For chlamydia	Doxycycline	100 mg by mouth 2 times daily for 7 days	2,800
Tetracycline		500 mg by mouth 4 times daily for 7 days	1,540	1.66
Erythromycin		500 mg by mouth 4 times daily for 7 days	5,600	6.02
Range of total cost to treat syndrome			3,690-14,600	3.97-15.70
<u>Vaginal Discharge</u>				
For gonorrhoea and chlamydia		(see above)		
For trichomoniasis and bacterial vaginosis				
	Metronidazole	2 g by mouth as a single dose	225	0.24
	Metronidazole	400 mg by mouth 2 times daily for 7 days	315	0.34
For candidiasis	Miconazole	400 mg vaginally once daily for 3 days	7,300	7.85
	Clotrimazole	200 mg vaginally once daily for 3 days		
	Generic		2,000	2.15
	Brand-name		8,000	8.60
	Nystatin <sup>c</sup>	100,000 U vaginally once daily for 12, 14, or 15 days (depending on pack)	1,650	1.77
Range of total cost to treat syndrome				
For vaginitis and cervicitis <sup>d</sup>			5,565-22,915	5.98-24.64
For vaginitis only <sup>e</sup>			1,875-8,315	2.02-8.94

\* Costs are based on the median price found in a survey of 16 retail pharmacies

<sup>b</sup> NA=not available in pharmacies surveyed

<sup>c</sup> Nystatin vaginal tablets are sold in packs of 12, 14, or 15 tablets, depending on the brand. The World Health Organization recommends treatment with 100,000 U for 14 days.

<sup>d</sup> Treatment for vaginitis and cervicitis includes treatment for gonorrhoea, chlamydia, trichomoniasis, bacterial vaginosis, and candidiasis

<sup>e</sup> Treatment for vaginitis includes treatment for trichomoniasis, bacterial vaginosis, and candidiasis

Table A 3 Costs for syndromic treatment of genital ulcer disease and lower abdominal pain, based on cost of drugs in retail pharmacies in Accra.<sup>a</sup>

Syndrome	Drug choices	Course of treatment	Cost (in Cedi)	Cost (in US \$)
<u>Genital Ulcer</u>				
For syphilis in persons not allergic to penicillin				
	Benzathine penicillin	2.4 million U IM during one visit	NA <sup>b</sup>	NA
For syphilis in men and nonpregnant women allergic to penicillin				
	Doxycycline	100 mg by mouth 2 times daily for 15 days	6,000	6.45
	Tetracycline	500 mg by mouth 4 times daily for 15 days	3,300	3.55
For syphilis in pregnant women allergic to penicillin				
	Erythromycin	500 mg by mouth 4 times daily for 15 days	12,000	12.90
For chancroid				
	Erythromycin	500 mg by mouth 3 times daily for 7 days	4,200	4.52
	Ciprofloxacin	500 mg one dose only	2,150	2.31
	Ceftriaxone	250 mg IM as a single dose	NA	NA
	Co-trimoxazole <sup>c</sup>	2 tablets two times daily for 7 days	840	0.90
Range of total cost to treat syndrome (persons not allergic to penicillin)			NA	NA
<u>Lower Abdominal Pain</u>				
For gonorrhoea and chlamydia		(see Table 5)		
For anaerobic bacteria				
	Metronidazole	400 mg by mouth 2 times daily for 10 days	900	0.97
Range of total cost to treat syndrome			4,590-15,500	4.93-16.67

<sup>a</sup> Costs are based on the median price found in a survey of 16 retail pharmacies.

<sup>b</sup> NA=not available in pharmacies surveyed

<sup>c</sup> A tablet of co-trimoxazole consists of trimethoprim 80 mg and sulfamethoxazole 400 mg

Table A 4 Wholesale prices on the international market of antibiotics used to treat sexually-transmitted diseases

Drug	Dosage form	Price (in US \$)
Benzathine penicillin	2.4 million vial	0.39 <sup>a</sup>
Cefixime	200 mg tablet	1.50 <sup>a</sup>
Ceftriaxone	250 mg vial	3.50 <sup>a</sup>
Ciprofloxacin	500 mg tablet	0.40 <sup>a</sup>
Clotrimazole	pack of 6 100 mg vaginal tablets	0.70 <sup>b</sup>
Co-trimoxazole	80 mg trimethoprim/400 mg sulfamethoxazole tablet	0.01274 <sup>a</sup>
Doxycycline	100 mg capsule	0.01433 <sup>a</sup>
Erythromycin	250 mg tablet	0.0386 <sup>a</sup>
Kanamycin	2 g vial	0.50 <sup>a</sup>
Metronidazole	250 mg tablet	0.00726 <sup>a</sup>
Miconazole	200 mg vaginal ovule	1.26 <sup>c</sup>
Norfloxacin	400 mg tablet	NA <sup>d</sup>
Nystatin	pack of 15 100,000 IU vaginal tablets	0.71 <sup>a</sup>
Spectinomycin	2 g vial	1.50 <sup>a</sup>
Tetracycline	250 mg capsule	0.0101 <sup>a</sup>

<sup>a</sup> Price from UNICEF Supply Division (Copenhagen)

<sup>b</sup> Price from International Dispensary Association, Amsterdam, Netherlands

<sup>c</sup> Price from Lande R Controlling Sexually Transmitted Diseases. Population Reports, Series L, No 9 Baltimore, Johns Hopkins School of Public Health, Population Information Program, June 1993

<sup>d</sup> NA=price not available

Table A 5 Costs for syndromic treatment of urethral discharge and vaginal discharge, based on the wholesale price of drugs in the international market<sup>a</sup>

Syndrome	Drug choices	Course of treatment	Cost (in US \$)
<u>Urethral Discharge</u>			
For gonorrhoea	Cefixime	400 mg as a single dose	3.00
	Ceftriaxone	250 mg IM as a single dose	3.50
	Ciprofloxacin	500 mg by mouth as a single dose	0.40
	Norfloxacin	800 mg as a single dose	NA <sup>b</sup>
	Spectinomycin	2 g IM as a single dose	1.50
For chlamydia	Kanamycin	2 g IM as a single dose	0.50
	Doxycycline	100 mg by mouth 2 times daily for 7 days	0.20
	Tetracycline	500 mg by mouth 4 times daily for 7 days	0.57
	Erythromycin	500 mg by mouth 4 times daily for 7 days	2.16
Range of total cost to treat syndrome			0.60-5.66
<u>Vaginal Discharge</u>			
For gonorrhoea and chlamydia		(see above)	
For trichomoniasis and bacterial vaginosis			
	Metronidazole	2 g by mouth as a single dose	0.06
	Metronidazole	400 mg by mouth 2 times daily for 7 days	0.20
For candidiasis	Miconazole	200 mg vaginally once daily for 3 days	3.78
	Clotrimazole	200 mg vaginally once daily for 3 days	0.70
	Nystatin	100,000 U vaginally once daily for 15 days <sup>c</sup>	0.71
Range of total cost to treat syndrome			
	For vaginitis and cervicitis <sup>d</sup>	..	1.36-9.64
	For vaginitis only <sup>e</sup>	.	0.76-3.98

<sup>a</sup> Costs are drawn from several listings and are approximate

<sup>b</sup> NA=not available

<sup>c</sup> UNICEF Supply Division sells nystatin vaginal tablets in packs of 15 tablets. The World Health Organization recommends treatment with 100,000 U for 14 days

<sup>d</sup> Treatment for vaginitis and cervicitis includes treatment for gonorrhoea, chlamydia, trichomoniasis, bacterial vaginosis, and candidiasis

<sup>e</sup> Treatment for vaginitis includes treatment for trichomoniasis, bacterial vaginosis, and candidiasis

Table A 6 Costs for syndromic treatment of genital ulcer disease and lower abdominal pain, based on the wholesale price of drugs in the international market<sup>a</sup>

Syndrome	Drug choices	Course of treatment	Cost (in US \$)
<u>Genital Ulcer</u>			
For syphilis in persons not allergic to penicillin			
	Benzathine penicillin	2.4 million U IM during one visit	0 39
For syphilis in men and nonpregnant women allergic to penicillin			
	Doxycycline	100 mg by mouth 2 times daily for 15 days	0 43
	Tetracycline	500 mg by mouth 4 times daily for 15 days	1 21
For syphilis in pregnant women allergic to penicillin			
	Erythromycin	500 mg by mouth 4 times daily for 15 days	4 63
For chancroid			
	Erythromycin	500 mg by mouth 3 times daily for 7 days	1 62
	Ciprofloxacin	500 mg one dose only	0 40
	Ceftriaxone	250 mg IM as a single dose	4 00
	Co-trimoxazole <sup>b</sup>	2 tablets two times daily for 7 days	0.36
Range of total cost to treat syndrome (persons not allergic to penicillin)			0 75-4.39
<u>Lower Abdominal Pain</u>			
For gonorrhoea and chlamydia		(see Table 8)	
For anaerobic bacteria			
	Metronidazole	400 mg by mouth 2 times daily for 10 days	0 29
Range of total cost to treat syndrome.			0 89-5 95

<sup>a</sup> Costs are drawn from several listings and are approximate

<sup>b</sup> A tablet of co-trimoxazole consists of trimethoprim 80 mg and sulfamethoxazole 400 mg

Table A 7 Costs for syndromic treatment of sexually-transmitted diseases using drugs recommended for addition to the Essential Drug List and National Formulary, based on cost of drugs in the international market vs. retail pharmacies in Accra <sup>a</sup>

Syndrome	Drug choices	Course of treatment	Wholesale International Market Price (in US \$)	Retail Pharmacy Price (in US \$)
<u>Urethral Discharge</u>				
For gonorrhoea	Ciprofloxacin	500 mg by mouth as a single dose	0 40	2 31
For chlamydia	Doxycycline	100 mg by mouth 2 times daily for 7 days	0 20	3 01
Total cost to treat syndrome ...			0.60	5 31
<u>Vaginal Discharge</u>				
For gonorrhoea and chlamydia		(see above)		
For trichomoniasis and bacterial vaginosis	Metronidazole	2 g by mouth as a single dose	0 06	0.24
For candidiasis	Clotrimazole (Generic)	200 mg vaginally once daily for 3 days	0.70	2 15
Total cost to treat syndrome				
For vaginitis and cervicitis <sup>b</sup>			1 36	7 70
For vaginitis only <sup>c</sup>			0.76	2 39
<u>Genital Ulcer</u>				
For syphilis in persons not allergic to penicillin				
	Benzathine penicillin	2 4 million U IM during one visit	0.39	0 39 <sup>d</sup>
For chancroid	Erythromycin	500 mg by mouth 3 times daily for 7 days	1.62	4 52
Total cost to treat syndrome (persons not allergic to penicillin)			2.01	4 91
<u>Lower Abdominal Pain</u>				
For gonorrhoea and chlamydia		(see above)		
For anaerobic bacteria	Metronidazole	400 mg by mouth 2 times daily for 10 days	0.29	0 97
Total cost to treat syndrome ..			1.05	6 28

<sup>a</sup> Wholesale international-markets prices are drawn from several listings and are approximate Retail pharmacy prices are based on the median price found in a survey of 16 retail pharmacies in Accra.

<sup>b</sup> Treatment for vaginitis and cervicitis includes treatment for gonorrhoea, chlamydia, trichomoniasis, bacterial vaginosis, and candidiasis

<sup>c</sup> Treatment for vaginitis includes treatment for trichomoniasis, bacterial vaginosis, and candidiasis

<sup>d</sup> Benzathine penicillin 2 4 million U/vial was not available in the pharmacies surveyed For purposes of comparison, the wholesale international-market price is used for the retail pharmacy price