

# SEXUALLY TRANSMITTED INFECTIONS IN SUB-SAHARAN AFRICA



## THE USE AND EFFECTIVENESS OF TREATMENT KITS

## Acknowledgements

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This report is available in English and French through [www.PSI.org](http://www.PSI.org) For additional information, English or French copies, please contact:

**PSI/Washington**  
1120 19th Street, NW  
Suite 600  
Washington, DC 20036 USA  
Telephone: (202) 785-0072  
Fax: (202) 785-0120  
Email: [generalinfo@psiwash.org](mailto:generalinfo@psiwash.org)  
[www.psi.org](http://www.psi.org)

**PSI/Europe**  
Douglas House 1st Floor  
16-18 Douglas Street  
London SW1P 4PB  
UK  
Telephone: +44 (0)20 7834 3400  
Fax +44 (0)20 7834 4433  
Email: [info@psieurope.org.uk](mailto:info@psieurope.org.uk)  
[www.psi.org/psi-europe.htm](http://www.psi.org/psi-europe.htm)

PSI is an international nonprofit organization dedicated to improving the health of low-income populations around the world. PSI operates AIDS prevention, family planning, and maternal and child health social marketing programs in more than 50 developing countries. PSI uses commercial marketing techniques to provide affordable health products and services through private sector outlets, along with a variety of communication techniques to encourage healthy behavior among target populations.

AIDSMark is a five-year, world-wide program, started in 1997, that uses social marketing to combat the spread of HIV/AIDS and other STIs.

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# Acronyms

- **AIDS** Acquired Immune Deficiency Syndrome
- **AMREF** African Medical Research Foundation, conducted provider training in Uganda
- **CMS** Commercial Market Strategies, USAID-funded private sector family planning and health project
- **HIV** Human Immunodeficiency Virus
- **IEC** Information, education, and communications
- **MoH** Ministry of Health
- **MSTOP** Brand name of PPST kit in Cameroon
- **NDA** National Drug Authority in Uganda
- **NGO** Non-governmental Organization
- **OTC** Over-the-counter, drugs sold lawfully without prescription
- **PPST** Pre-packaged STI treatment
- **PSI** Population Services International
- **STD** Sexually transmitted disease
- **STI** Sexually transmitted infection
- **SOMARC** Social Marketing for Change, USAID-funded project managed by The Futures Group International
- **TAC** Technical Advisory Committee
- **UNAIDS** United Nations Joint Program on HIV/AIDS Prevention
- **USH** Uganda Shilling
- **USAID** United States Agency for International Development
- **WHO** United Nations World Health Organization
- **\$** US dollar

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## Summary

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**P**reventable, curable sexually transmitted infections (STIs) continue to severely compromise the health of people in sub-Saharan Africa. Evidence over the past decade has revealed that the presence of an STI can also make it easier for the Human Immunodeficiency Virus (HIV) to pass from one person to another. Because the treatment of STIs can slow HIV transmission rates while improving overall public health, affordable and sustainable STI services should be incorporated into national public health policies and strategies.

Given the limited resources available in many countries, syndromic case management using pre-packaged STI treatment (PPST) kits can increase access to effective STI treatment. Syndromic management can be used outside the clinical setting, and in clinical settings where no laboratory diagnostics are available, to effectively and safely treat several STI syndromes. PPST kits can provide all treatment essentials in one package, improving adherence to proper and full treatment, prevention, and partner referral. In addition, the social marketing of PPST kits, especially with generic drugs, makes them affordable to the general public and highly cost-effective compared to existing treatment practices.

Syndromic management with PPST kits can offer a “one-stop shopping” intervention to improve STI treatment. Currently in sub-Saharan Africa, the only application of STI syndromic management with social marketed PPST kits is the treatment of gonococcal and chlamydial ure-

thritis in men. However, it is possible to treat female sexual partners of men with urethritis, or to design a PPST kit to treat other STI syndromes in men and women, although diagnosis might require a clinical exam.

A review of pilot PPST programs in sub-Saharan Africa reveals several key ingredients to program success, including formative research, provider training, targeted distribution, consistent monitoring, a permissive regulatory environment, affordability, and advocacy, information, education, and communications (IEC). Advocacy among the governmental regulatory authorities and private sector health providers also may be necessary: authorities are concerned with controlling the distribution of antibiotics to avoid an emergence of drug-resistant strains; providers, in addition to ensuring the provision of appropriate medical care, are concerned with the viability and profitability of their practices. Sufficient time and funding for program development, advocacy, introduction, and evaluation are generally the most significant considerations for any PPST intervention.

Social marketing PPST kits through private sector outlets such as pharmacies and drug sellers has the potential to achieve significant health impact. Investment in blister packaging discourages kit cannibalization and facilitates treatment adherence. The social marketing organization can control the quality of inputs, and creative IEC and promotional activities can encourage



men to seek treatment in a timely manner and notify their sexual partners, thereby increasing program reach. By training private providers and distributing treatment through the private and commercial sector outlets where people currently seek treatment, the social marketing of PPST kits holds promise as an effective and affordable method to deliver necessary STI treatment services, especially for men.

The introduction of PPST kits in a setting that has already embraced syndromic case management<sup>1</sup> and an essential drug list including World Health Organization-recommended antibiotics for treating STIs—coupled with the use of generic drugs—could result in an affordable kit independent of donor subsidies. Syndromic management using PPST kits is feasible on a drug cost-recovery basis. PPST kits can be an important part of an overall national strategy for improved STI treatment and management, and consequently, reduced HIV infection. The kits can be introduced in existing health care services; it is not necessary to create a new service-delivery infrastructure. For all PPST programs, reaching female sexual partners remains an important challenge.

## Introduction

**E**ach year, Africans living south of the Sahara incur an estimated 65 million new cases of curable sexually transmitted infections (STIs)<sup>2</sup>, excluding chancroid<sup>3</sup>.

Approximately 44% of these cases are gonorrhea and chlamydial infection. For every 1,000 sub-Saharan Africans between the ages of 15 and 49, this translates to 245 new cases per year [28]. STIs are more than unpleasant; left untreated they can also lead to lasting side effects most severe in women and children, including infertility, ectopic pregnancy, and congenital infections.

Evidence over the past decade has also revealed that the presence of an STI makes it easier for Human Immunodeficiency Virus (HIV) to pass from one person to another [19]. Chancroid, chlamydial infection, gonorrhea, syphilis, and trichomoniasis may increase the risk

of HIV transmission by two to nine times [22]. However, the number of new HIV infections attributable to a “co-factor effect” of curable STIs may decline as the HIV epidemic matures because the number of individuals with HIV infection increases, and therefore the potential exposure to HIV from any sexual contact increases [28]. Furthermore, the prevalence of non-curable STIs (herpes simplex virus) also increases.

Even in countries with high HIV prevalence, the STI co-factor effect is noteworthy. Subgroups in these countries, for example adolescents, may have high rates of STIs with low HIV prevalence, putting them at increased risk of HIV infection. Thus, for these subgroups, accessible, affordable and effective STI treatment and prevention programs may reduce HIV infections [10].

Given that the treatment of STIs can slow HIV infection spread while improving overall public health, affordable and sustainable STI services are important to national public health policies and strategies. To have the greatest impact, it is necessary to implement prevention activities and to find and treat cases as soon as possible. Syndromic case management of STIs is a viable case management option in developing country settings with limited availability of trained staff, appropriate drugs, and diagnostic tools. Pre-packaged STI treatment (PPST) kits can reinforce and enhance the use of syndromic management.

Syndromic management can be used to manage a range of STI syndromes. The syndrome of urethral discharge in men is very specific for an infection with either gonorrhea or chlamydia. Therefore, the syndromic management approach to urthritis in men is accurate and simple.



Proper and consistent use of condoms is essential to STI treatment and prevention.

<sup>1</sup> It should be noted that now, 10 years after the beginning of the pilot intervention in Cameroon, syndromic management is familiar and accepted by most governments in sub-Saharan Africa, and is part of the regular training of health personnel in some countries.

<sup>2</sup> In this report, the term STIs is used to refer to all sexually transmitted diseases and infections, excluding HIV, unless otherwise stated.

<sup>3</sup> According to WHO, chancroid estimates cannot be obtained by using the same method as for other STIs (i.e. syphilis) because of the poor understanding of the epidemiology and natural history of the disease, and the absence of an accurate test.



## What is Syndromic Case Management?

STI syndromic case management has been promoted as a patient management tool since the early 1990s. It does not rely on clinical diagnosis or laboratory procedures for diagnosis, and therefore offers advantages in resource-poor settings. Most front-line health care providers can be trained to effectively implement it. Syndromic case management of STIs is designed to

- provide rapid and effective treatment
- advise on adherence to proper and full treatment
- educate about future risk reduction
- promote and provide condoms (always included in a PPST kit) to prevent reinfection
- encourage partner notification.

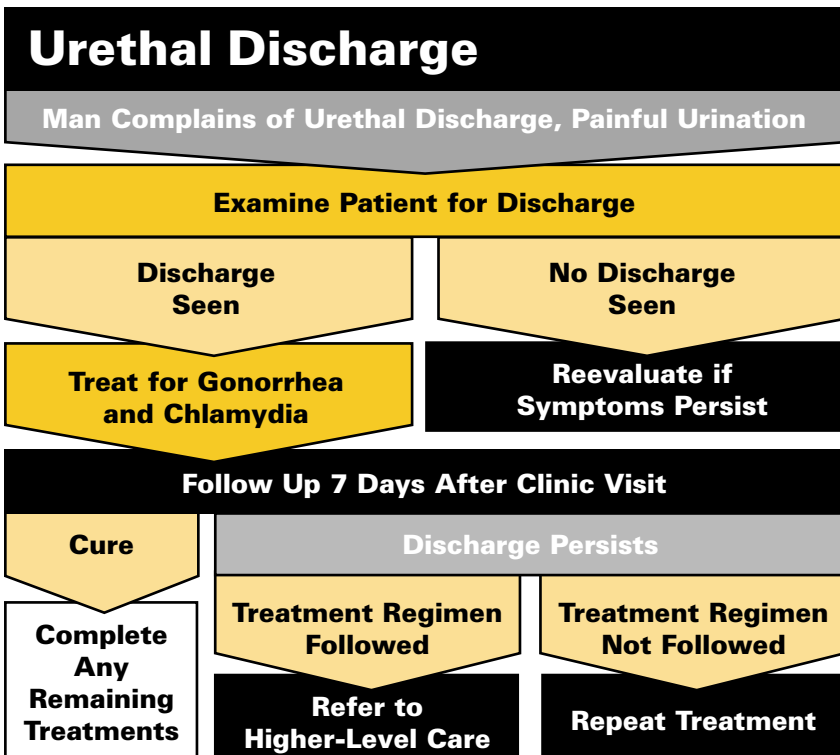
observations of clinical signs to correctly recognize a syndrome and effectively manage all causes of that syndrome, and allows for complete treatment at the first visit.

Standardized flowcharts assist providers in reaching a diagnosis of a syndrome and recommending a treatment that covers all key causes of the particular condition. Once a syndrome is recognized, the provider prescribes treatment and counsels the patient to prevent reinfection. Counseling includes an emphasis on consistent condom use, taking the full course of medication, and ensuring treatment for sexual partners.

Limitations of syndromic STI management include having

- more accuracy for some syndromes than others
- less accuracy for managing STIs in women because many have no symptoms
- the requirement of comprehensive provider training and monitoring.

- make a rapid and accurate identification
- Syndromic management relies on patient symptoms and provider



### Why the syndrome of urethral discharge...

- Most men with gonococcal or chlamydial urethral infection will have symptoms—painful urination (dysuria) and/or urethral discharge—three to 10 days after infection.
- Symptoms of dysuria and urethral discharge in men are most likely caused by STIs, specifically *N. gonorrhoeae* and *C. trachomatis*.
- Consequently, the syndrome of urethritis (dysuria and urethral discharge) is a good target for interventions due to the ease of detection through syndromic management, and due to patients' perception of urgency for treatment.

- A significant number of men with urethritis do not seek medical care in clinics but rather purchase drugs directly, so they often receive incorrect treatment and are not cured.
- The recommended treatment for urethritis is a simple regime of antibiotics taken orally to treat both *N. gonorrhoeae* and *C. trachomatis*.<sup>4</sup>
- For syndromes other than urethritis, recommended treatment may include a longer drug regime or injections that require multiple visits to the health clinic.

- Common STI symptoms in women such as abdominal pain, genital pain, and vaginal discharge have several causes other than STIs, necessitating a clinical exam and laboratory analysis for correct diagnosis and treatment.
- Pregnant or lactating women should not take certain urethritis treatment because it could harm a fetus or nursing child.

Product insert information, promotions, and other communications can be used to advise female partners to seek a medical examination to confirm diagnosis rather than directly buy a kit. However, clinic visits are more expensive than kits.

### ...and not STIs in women

- Up to 70% of women with an STI may not have any symptoms.

## What is a PPST Kit?



### Contents

- **Antibiotics (preferably generic) to treat the STI pathogens causing the syndrome.**
- **Sufficient condoms for the duration of the treatment.**
- **At least two partner referral cards for partner notification.**
- **An STI and product educational and informational leaflet.**

### Advantages

- **Provides all treatment and prevention essentials in one convenient package.**

- **Improves adherence to proper and full treatment, prevention and referral.**
- **Blister-packed antibiotics contain full regimen and discourage "cannibalization" (selling parts of the kit separately), which may be a concern of national drug regulatory authorities.**
- **Social marketing can increase knowledge of STIs as well as access, affordability, and usage of correct treatment.**

<sup>4</sup> WHO protocols include several single-dose, oral or injectable antibiotics to cure gonorrhoea, and four different oral multi-day antibiotics to cure chlamydial infection. Ideally, a drug regimen with 95% cure rates should be used. Local or regional anti-microbial resistance information should be utilized when choosing an antibiotic.





In many countries of sub-Saharan Africa, there is a limited or inconsistent drug supply in the public sector, and drugs available in the private sector tend to be very expensive because of import duties and other tariffs. As such, the more expensive drugs have a higher profit margin; the recommended treatment is then out of reach for many who are infected. Furthermore, providers may not prescribe the appropriate treatment, or clients may not have sufficient funds to purchase the full treatment regime at one time. Syndromic management of urethritis ensures a standardized approach to the management of the syndrome. A PPST kit then provides the correct drugs in the proper dosage at an affordable price, in a convenient location.

Experiences with social marketing PPST kits in Cameroon and Uganda are the focus of this report. It is hoped that a comparative review of these two projects will inform the introduction of PPST kits in other countries. Additional examples are given from the public sector in South Africa and Mozambique, and from a West Africa regional program that uses the private, public, and non-governmental organization (NGO) sectors. United States Agency for International Development (USAID) field missions, bilateral and multilateral donor organizations, host governments, professional medical and pharmaceutical associations, and NGOs may use the lessons derived from these examples in designing PPST activities, with the ultimate aim of improving STI case management and decreasing rates of STIs and, indirectly, HIV.



***In many countries of sub-Saharan Africa, there is a limited or inconsistent drug supply in the public sector, and drugs available in the private sector tend to be very expensive because of import duties and other tariffs.***

## What is Social Marketing?

**Social marketing is designed to improve the health of low-income people by promoting healthy behavior, offering health products and services at affordable prices, and motivating people to use them. Social marketing is meant to increase both the supply of and demand for health products and services. Condom social marketing has become central to HIV and Acquired Immune Deficiency Syndrome (AIDS) prevention programs around the world, as well as an important part of family planning and maternal and child health programs in some countries.**

**Products are sold, rather than given away, so that people will value and use them and sellers can receive a small profit as incentive. The prices are usually subsidized so they are afford-**

**able to economically disadvantaged populations. Social marketing programs receive donated products (or funds with which to buy them) and then sell the products attractively packaged under a brand name. The products are sold in existing outlets—including pharmacies, drug shops, clinics, and neighborhood retail outlets—frequented by low-income people every day.**

**Social marketing relies on promotional and educational campaigns to encourage people to adopt healthy practices, including the correct use of the products sold and services provided. These communication campaigns may use a wide range of media, including radio, television, magazines, posters, billboards, mobile video units, live theater performances, and interpersonal communications.**

## Social Marketing Interventions

**T**he two PPST social marketing projects to be reviewed were designed to address comparable problems. Cameroon and Uganda were both experiencing an increasing incidence of urethritis. Treatment-seeking behavior research showed high levels of self-treatment, often resulting in incomplete or incorrect drugs or dosages, which could lead to widespread use of ineffective or inappropriate antibiotics. Self-treatment also excluded counseling to prevent future reinfection, to inform and treat partners, and to learn the importance of condom use. Mass media advertising of brand-name drugs was illegal in both countries.

The introduction of social marketed PPST kits was a direct response to this situation. In both Cameroon and Uganda, the target group was men aged 18 to 35. Evaluations of both interventions incorporated focus groups, in-depth interviews, and mystery-client methodologies. The general objectives of the interventions were also alike:

- Increase access to effective treatment for urethritis.
- Promote condom use.
- Strengthen partner referral and therefore increase treatment of asymptomatic women.
- Promote client adherence to full and proper treatment.
- Provide health education for risk reduction.
- Enhance symptom recognition and early reporting for treatment through efficient patient counseling.

- Strengthen proper diagnosis and prescription of appropriate drugs through use of the kit.

Although the health needs and objectives behind the two programs were similar, many differences emerged in their design, implementation, and impact. Following a discussion of the Cameroon and Uganda social marketing programs, a summary of differences will be presented before moving on to review other PPST interventions.

### Cameroon MSTOP Pilot Project

With funding from USAID, Population Services International (PSI) and Family Health International implemented a PPST pilot project in the two largest cities in Cameroon from 1991 to 1994. The PPST kit was distributed

from July 1993 to April 1994. The intent of the program was to market an affordable, pre-packaged kit to treat gonococcal and chlamydial urethral infection in men and cervicitis in their female partners.

The 10-day PPST kit was called MSTOP. The name reflected its purpose: to stop the spread of STIs (*MST* is the French acronym for *maladies sexuellement transmissibles*). MSTOP contained two tablets of cefuroxime-axetil (500 mg each) taken as a single dose to treat gonorrhea, 20 tablets of doxycycline (100mg each) taken one tablet twice daily for 10 days to treat chlamydial infection, an educational and informational leaflet, eight condoms, and two partner referral cards.

The final project evaluation revealed clients' enthusiasm for the product. Eighty-six percent of users



The Cameroon MSTOP kit.



were pleased with the presentation and contents of the kit. An overwhelming majority of 82% reported adherence to proper and full treatment, over half reported notifying all their partners of their infection, and 84% reported using condoms during the duration of the treatment [25]. These outcomes were measured through quantitative surveys and qualitative methods, with MSTOP users and providers. The results were achieved despite numerous obstacles encountered during both design and implementation of the MSTOP project:

- 1 Lack of supportive national policies. At the time of the pilot, there was no national STI policy for syndromic management and standardized treatment protocol in Cameroon.
- 2 Limited choice of antibiotics. The government did not allow the importation and sale of generic drugs in the commercial sector. Consequently, more expensive, branded doxycycline was used in the kit. Cefixime—a single-dose, third-generation antibiotic included in World Health Organization (WHO) protocols to treat gonorrhea—was not registered in Cameroon. Therefore, the kit included a second-generation cephalosporin, which had a shorter half-life and therefore risked a more rapid emergence of resistance.
- 3 Limited choice of sales outlets. Although the kit was originally slated for sale in private clinics, a change in Ministry of Health (MoH) personnel and policy resulted in the kit being sold only in pharmacies by prescription, and in a limited number of
- 4 Lack of commitment by MoH officials and medical associations. The new MoH officials agreed with physicians' and pharmacists' associations to oppose using syndromic management to diagnose and treat STIs and dispensing antibiotics without a prescription. The project was viewed as an external intervention without Cameroonian ownership.
- 5 Lack of endorsement by providers. A total of 81 health care providers from government clinics and three private pharmacies participated in a half-day training course in syndromic management of urethritis, and were invited to prescribe MSTOP to male patients with the condition. However,
  - many health care providers were not convinced of the *efficacy* of the MSTOP kit because syndromic management was a new concept, dispensing antibiotics without laboratory examination was unprecedented, and the drugs selected were not on the essential drug list;

public sector clinics catering to university students and the military (these two sub-populations were considered to have higher rates of STI infection than the general population). Thus, access to kits was restricted to a limited geographic area and did not meet the needs of men who did not seek care in public sector clinics. Because the MSTOP pilot project had limited scope, it is impossible to know whether the MoH eventually would have allowed the kit to be sold over-the-counter (OTC, without a prescription).

**Treatment-seeking behavior research showed high levels of self-treatment, often resulting in incomplete or incorrect drugs or dosages, which could lead to widespread use of ineffective or inappropriate antibiotics. Self-treatment also excluded counseling to prevent future reinfection, to inform and treat partners, and to learn the importance of condom use.**

- providers had no profit *incentive* to dispense the kit rather than other, more expensive medications;
  - providers perceived MSTOP to have more outside than local *involvement*; and
  - providers did not prescribe MSTOP with *consistency*.
- 6 Lack of consensus among key stakeholders. Full agreement regarding project objectives was not achieved. Some key stakeholders were concerned that social marketing a pre-packaged kit would lead to availability of kits on every corner. Others wanted to use MSTOP to improve delivery of primary health care services, thereby limiting its distribution to clinics. MSTOP's role as a complement to, rather than a replacement for, primary health care in the formal sector was not understood [9]. Project implementers actively worked to build consensus, considering the legitimate concerns raised by medical and pharmaceutical representatives. However, the change of

personnel within the MoH resulted in loss of a key advocate from within the health community.

Most of the specific objectives of the MSTOP pilot project were met, but only 1,421 PPST kits were sold, and plans for expansion were not realized. The high level of client interest and potential for improved STI services, as well as the experience with obstacles, informed the subsequent social marketing project in Uganda, and offers guidelines for other PPST activities.

### Uganda Clear Seven Pilot Project

Social Marketing for Change (SOMARC) and Commercial Market Strategies (CMS) implemented a USAID-funded PPST pilot project in Uganda from 1996, when the country assessment and recommendations to introduce a PPST kit were conducted, to 1999. The kits were distributed from January through October 1999. Implemented in four urban perimeter/rural districts, the project was designed to test ways to

improve client adherence to STI treatment by offering the full course of the correct drugs through social marketing. Kits were distributed through Class C drug shops<sup>5</sup>, private clinics, and pharmacies. Some 80% of these outlets were already distributing social marketed condoms, facilitating the introduction of the PPST product.

The PPST intervention in Uganda incorporated a relatively comprehensive evaluation component, designed to determine whether the introduction of the OTC kit improved access to effective, affordable treatment, and whether the treatment was taken correctly. Data were also collected on the impact of educational materials and activities, provision of condoms and partner notification cards [27]. The evaluation of the pilot phase found the program to be meeting most of its objectives, and expansion of the PPST intervention began in September 2000. Beginning with the four pilot areas, districts will be added until the program reaches nationwide coverage.

As the brand name implies, the "Clear Seven" PPST kit clears infections in seven days. Clear Seven contains one tablet of ciprofloxacin (500mg) taken as a single dose to treat gonorrhea; 14 tablets of doxycycline (100 mg each) taken one tablet twice daily for seven days to treat chlamydial infection; seven condoms; one patient informational leaflet in English and two other commonly spoken languages; and three partner referral cards in the same three languages. The pilot project was authorized to market the kit only to men. Those between the ages

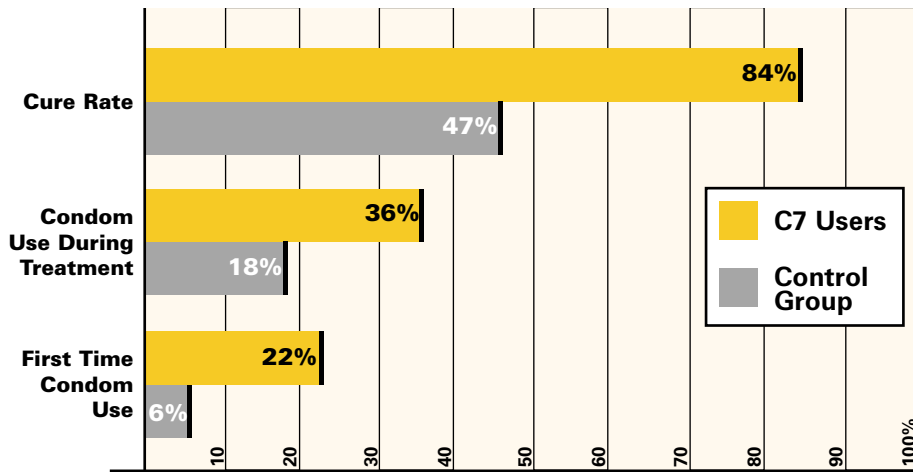


The Uganda Clear Seven kit.

<sup>5</sup> Class C drug shops are licensed to distribute simple medicines such as analgesics and cough mixtures. Drug shops are not authorized to dispense or prescribe antibiotics. A drug shop owner must have a qualification in a relevant pharmaceutical, medical, veterinary, nursing, or other paramedical field approved by the Government of Uganda National Drug Authority. The NDA granted SOMARC/CMS a special exemption to allow Clear Seven to be sold OTC through drug shops on a pilot basis.



## Clear Seven Pilot Results



Evaluation of the pilot program found that Clear Seven users had significantly higher STI-cure and condom-use rates compared to the control group.

of 15 and 49, especially younger men aged 18 to 35, were targeted.

Drawing lessons directly from the experiences of the MSTOP project, SOMARC and CMS staff in Uganda overcame the six primary obstacles encountered in Cameroon:

- 1 Supportive national policies. The MoH had already adopted a policy of syndromic case management for STIs, standardized treatment protocols adopted from WHO guidelines were in place, and the drugs in the treatment protocols were on the essential drug list.
- 2 Choice of antibiotics and generics. The 1996 project feasibility study had confirmed that the policy and regulatory environment was supportive. There were no lengthy debates with health officials and physicians regarding which drugs to include in a PPST kit. In addition, there were no

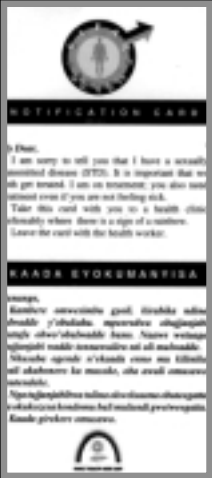
restrictions on the commercial sale of generic antibiotics. Furthermore, there was an abundant supply of generic STI medication in the country, due to an ongoing World Bank-funded project with the MoH. In fact, Clear Seven inspired strong private-public collaboration, as when the World Bank and the MoH agreed to donate sufficient antibiotics for the pilot phase. However, the MoH raised concerns about the possible emergence of antibiotic resistance to the drugs in the kit. As this continues to be a concern, the expansion of Clear Seven will be closely monitored and controlled.

- 3 Choice of sales outlets. After lengthy negotiations, the pilot project was given authorization to sell the PPST kits without a prescription through legally registered Class C drug shops, pharmacies and clinics. Clear Seven project staff surveyed eligible

drug shops in the target districts and, through the application of specific criteria, selected invitees for training in syndromic management<sup>6</sup>. Only those 250 shops with staff who had passed the training were authorized to sell the kits. In addition, nine pharmacies and 90 private clinics were authorized to distribute Clear Seven. The project implementers were responsible for monitoring and supervising all of the outlets, and assuring consistent supply of the kits.

- 4 Commitment by MoH officials and medical associations. Key MoH officials were members of a Technical Advisory Committee (TAC) from the beginning of the project. This strategy proved successful in bringing strong MoH advocates for PPST into negotiations with the National Drug Authority (NDA) and other governmental agencies. Professional medical associations did not pose any resistance to the introduction of PPST kits.
- 5 Commitment by providers. Clear Seven was sold OTC by pharmacies, clinics, and Class C drug shop staff who had passed the training, thus the product providers were vested in its success. Although most of the drug shops had offered an alternative treatment for gonorrhea or chlamydial infection, appropriate dosage had not been assured. Clear Seven was prescribed consistently, and was generally sold at the recommended retail price.
- 6 Consensus among key stakeholders. Full agreement regarding project objectives was achieved through participation in the TAC.

<sup>6</sup> Only those drug shops that were legally registered with the NDA, had employed staff with formal medical training, and were willing to participate in the training and the pilot project were invited to attend.



The negligible number of referral cards collected at these clinics did not necessarily indicate that the men did not give truthful information about referring their female partners, but made it difficult to conclude that the referral cards had an impact.

However, the government regulatory authority was concerned because

- it was not legal to dispense antibiotics OTC
- providers could be tempted to cannibalize the kit and sell the contents
- there was no equivalent kit for women.

One of the key objectives of the Clear Seven pilot project was to reach sexual partners of clients through referral to a participating clinic. This was to be accomplished through provider counseling, combined with the partner referral cards included in all PPST kits. For various reasons, however, it is difficult to measure the utility of referral cards. Although a female partner is supposed to bring her card to the referred clinic, she may also seek treatment without her referral card, or at a different location—most likely in the private sector, for greater perceived confidentiality [12]. The final evaluation of the pilot revealed that few drug shop personnel refused to sell the kit to women, and even fewer referred women for treatment at an appropriate health unit [13].

In the final evaluation of the Clear Seven pilot, a higher-than-expected 54% of men reported having informed their partners of their infections, and 36% reported having referred their partners to a clinic [13]. The negligible number of referral cards collected at these clinics did not necessarily indicate that the men did not give truthful information about referring their female partners, but made it difficult to conclude that the referral cards had an impact.

To strengthen the referral aspect of the program, in May 2000 the TAC and NDA approved the presumptive

treatment of the female sexual partners of men with urethritis. The revised training curriculum emphasizes contraindications and the importance of confirming that a female partner is not pregnant or breastfeeding before prescribing the Clear Seven kit. These changes are expected to result in more female sexual partners receiving treatment and counseling.

Final evaluation of the pilot phase also illustrated that treatment adherence improved to 93%, cure rate increased to 86%, and condom use during treatment doubled for Clear Seven users as compared to a control group. The evaluation found no evidence of sales of incomplete courses of treatment [12], which addressed concerns that if the kit price was considerably lower than the cost of the drugs sold individually, the kits would be cannibalized to resell the drugs. Meeting its objectives to date, Clear Seven has improved correct treatment of men with gonorrhea and chlamydial infections, and made treatment easier, more accessible, and less expensive.

### Summary of Differences

Although there were similarities in the Cameroon and Uganda social marketing PPST projects, the details differed significantly, offering an opportunity to draw lessons so that other STI/HIV management and prevention programs may benefit from their experiences. In turn, new PPST interventions can be more cost-effective and efficient in design and implementation. As reiterated in the following table and reflected in this report's Summary and Recommendations, much can be learned from the differences that directly influenced the outcomes of these two pilots.

## Summary of Differences: Social Marketing Interventions

	CAMEROON – MSTOP	UGANDA – CLEAR SEVEN
Cost of Kit	\$16.67 equivalent	\$1.33 equivalent
Government Support	<ul style="list-style-type: none"> <li>• Lack of policy support</li> <li>• Limited consensus among key stakeholders</li> </ul>	<ul style="list-style-type: none"> <li>• Supportive national policies</li> <li>• TAC promoted consensus</li> <li>• Drugs donated by World Bank-MoH STI Project</li> </ul>
Provider Involvement	<ul style="list-style-type: none"> <li>• Medical community not involved in design</li> <li>• Public sector distribution only</li> </ul>	<ul style="list-style-type: none"> <li>• Provider involvement through needs assessment</li> <li>• Private sector distribution only</li> <li>• Outlets already distributing other social marketing products</li> </ul>
Implementation Design	<ul style="list-style-type: none"> <li>• Trained 81 physicians, nurses and pharmacy staff</li> <li>• 22 public sector outlets and three pharmacies distributed kits</li> <li>• Sales were monitored for a 10-month period</li> <li>• Revenue was to be deposited into a revolving fund to replenish the stock of kits</li> </ul>	<ul style="list-style-type: none"> <li>• Trained staff of 250 legally registered drug shops, pharmacies, and clinics</li> <li>• Local promotional campaigns allowed</li> <li>• Sales were monitored for a six-month period</li> <li>• Creative use of existing media and informal education (see page 20)</li> </ul>
Results	<ul style="list-style-type: none"> <li>• 1,392 kits sold in 10 months</li> <li>• 86% of patients liked the kit</li> <li>• 82% reported full adherence</li> <li>• Over half reported notifying all their partners</li> <li>• 84% reported using condoms during treatment</li> <li>• Providers had concerns and did not prescribe the kit</li> <li>• Key stakeholders were reluctant to endorse the use of syndromic management and the kit</li> </ul>	<ul style="list-style-type: none"> <li>• 6,474 kits sold in 10 months in pilot districts</li> <li>• 154,426 kits distributed free nationally (ciprofloxacin was expiring)</li> <li>• Treatment adherence improved to 93%</li> <li>• Cure rate increased from 47% to 84%</li> <li>• Over half reported notifying their partners</li> <li>• Condom use during treatment doubled as compared to control group</li> <li>• First-time condom use nearly four times higher for kit users</li> </ul>

## Other PPST Interventions

**T**he lessons derived from social marketing interventions can be supplemented and refined by a brief review of other PPST projects. These examples come from a West Africa regional program integrating private, public, and non-governmental (NGO) elements, and the public sector in South Africa and Mozambique. Descriptions of each program will lead to a comparative summary, followed by a consideration of key PPST program components.

### West Africa Multi-Sector Project To Combat AIDS

Taking a regional, multi-sectoral approach to combat HIV/AIDS in



Bicycle vendors carry consumer goods, including condoms.

West Africa, a collaboration of various private, government, and NGO entities was arranged in 1996 by the *Centre de Cooperation Internationale en Sante et Developpement, Inc.*, of Quebec, Canada, with funding from the Canadian International Development Agency. It targets under-served urban areas and migratory and transit routes in seven countries: Benin, Burkina Faso, Côte d'Ivoire, Ghana, Guinea, Mali, and Senegal. Using both clinic-based and community-based strategies, the overall objective of the five-year intervention is to reduce the transmission of HIV among high-risk groups through syndromic control of STIs by

- reinforcing primary and community health networks
- giving priority to groups likely to adopt high-risk behaviors
- encouraging stakeholders to work on a self-sustaining basis.

The community participation objective promotes the importance and acceptability of STI control and prevention among populations served by the health centers, especially those at highest risk of STIs and HIV. The stakeholder strategy is included to ensure the constant availability of drugs essential to the treatment of STIs. In addition, an analysis of the essential drug supply mechanisms, networks, and tariff structures was completed in each country to design ways to reduce the cost of medicines.

In Côte d'Ivoire, for example, the program piloted seven different kits

to treat the most common STIs. Access to lab facilities enabled diagnosis of a wider range of syndromes. PPST kits were designed for urethritis, vaginal discharge, genital ulcers, and pelvic inflammatory disease, with different prescriptions for pregnant women. The pilot PPST kits were fabricated by the central pharmacy of the Ivoirian MoH and distributed to district-level warehouses, as are other essential medicines. Individual health clinics and centers were responsible for stocking their supplies from the district warehouses according to need. In the neighborhoods of Bouaké and Abidjan targeted by the pilot intervention, the kits were available only to clients with a prescription from a private or public sector pharmacy, clinic, or health center. A cost-recovery price was established for kits sold through clinics; on average a 10% margin was added to the cost of the kit [6]. Clients also retained the option to purchase the medication through a private pharmacy, with a prescription, for more money. Kits ranged in price—private clinics charged up to three times more than the public sector.

The PPST intervention in Côte d'Ivoire was primarily intended to integrate improved STI services into the existing health delivery systems. Its most positive result was the training of health care providers to enable more accurate diagnosis. The kits then ensured a proper treatment regime—drugs, dosage, and duration. However, the Ivoirian government's central pharmacy was not able to guarantee a constant supply





of all the drugs needed for the seven different kits, and the drugs procured had different expiration dates. As such, frequent stock outages were experienced.

The West Africa integrated, multi-sector approach includes training in syndromic management and provision of PPST kits as two components among many. It is a complex, multi-level, multi-partner project that carries relatively high administrative costs and requires a sophisticated management structure, making it difficult to replicate elsewhere.

### South Africa Public Sector

In Hlabisa District of KwaZulu Natal, South Africa, a program to introduce pre-packaged kits to treat several STIs in men and women was piloted through public sector clinics from September 1996 to December 1997. An operations research intervention, it was designed both to improve the quality of STI case management through the training of clinical nurses and introduction of STI-specific treatment kits, and to study the impact on STI case management. The project was developed and implemented by Hlabisa Hospital, the Center for Epidemiological Research in South Africa, the South Africa Medical Research Council, and The Johns Hopkins University School of Hygiene and Public Health in the US.

The goal of the intervention was to improve the public sector's capacity in

- correct diagnosis and treatment of STIs
- condom promotion and provision
- identification and treatment of partners



Two of the six South Africa kits.

- counseling to promote risk reduction.

The South Africa project included training 16 clinical nurses in syndromic management, as well as monitoring, supervising, and evaluating them through simulated patient visits to the participating primary care clinics where they worked. Because the providers had access to laboratory facilities, a wider range of STIs, among women as well as men, could be diagnosed and treated.

The project designed, introduced, and evaluated a set of PPST kits in six public sector clinics and, as a short pilot, in five private medical practices. Six different kits were developed to treat a variety of STIs based on the diagnosis of symptoms including urethritis, genital ulcers, female vaginal discharge, and pelvic inflammatory disease [30]. Each kit contained condoms and the appropriate drugs, a patient informational leaflet, and partner referral cards. Three different kits were designed to treat female vaginal discharge: the prescription depended on whether the woman was pregnant, and whether she was under or over age 30—criteria established by provincial STI treatment guidelines.

There were substantial improvements in the quality of STI case management as a result of the intervention. Prescription of proper drugs rose to 88%, as compared to 50% in non-intervention sites; adequate patient counseling, including partner referral and condom use, rose to 88% as compared to 12% in non-intervention sites; and clients reported that providers had positive attitudes and respect for privacy, reflecting a turnaround of two common complaints about the public sector.

### Mozambique Public Sector

There are almost no private sector medical services in Mozambique. To improve the quality of STI treatment services, PSI and the MoH designed an intervention for all 17 public sector health clinics in the capital city of Maputo. This activity was launched in 1999, funded by the European Union. The specific objectives are to

- improve data collection and analysis by health workers in Maputo
- introduce an attractive STI packet (a PPST kit without antibiotics) to encourage partner notification and referral to clinics



The Mozambique STI packet.

- implement information, education, and communications (IEC) activities to encourage treatment seeking and partner referral
- monitor the number of STI patients and referrals seeking treatment.

To date, the Mozambique project has trained health workers in communicating with STI patients, encouraging patients to refer their partners for treatment, and giving an STI packet to every patient with an STI. The packet contains two partner notification cards, condoms with instructions, and two STI informational leaflets, but does not include any drugs. The MoH is responsible for maintaining the supply of STI medicines through its regular, essential drug distribution to clinics and pharmacies, in addition to ensuring providers are trained in the syndromic case management of STIs. Preliminary results of the intervention indicate that STI treatment seeking is improving, and condom use and partner referrals are increasing.

**Comparative Summary**

In countries without an extensive private sector, PPST kits can improve efficiency and quality in the public sector. As seen in South Africa and Mozambique, providers are always trained medical staff (nurses, midwives, doctors, and pharmacists) who are likely to have previous exposure to syndromic management and are authorized to prescribe or dispense antibiotics. Because public sector interventions tend to be clinic-based with some laboratory facilities, a wider range of STIs, among women as well as men, may be diagnosed and treated.

PPST kits can be viable in the public sector setting if clinics and health centers are widespread and sufficiently staffed, if the drug distribution system minimizes stock outages, and if research indicates that people will seek STI services from the public sector. Social marketing can complement public sector distribution with educational and promotional activities.

To date, the Mozambique project has trained health workers in communicating with STI patients, encouraging patients to refer their partners for treatment, and giving an STI packet to every patient with an STI. The packet contains two partner notification cards, condoms with instructions, and two STI informational leaflets



## Comparative Summary: Other PPST Interventions

	WEST AFRICA	SOUTH AFRICA	MOZAMBIQUE
<b>Objectives</b>	<ul style="list-style-type: none"> <li>Reinforce primary and community health networks</li> <li>Give priority to groups likely to adopt high-risk behaviors</li> <li>Encourage stakeholders to work on a self-sustaining basis</li> </ul>	<p>Improve overall STI case management by building public sector capacity in</p> <ul style="list-style-type: none"> <li>Correct diagnosis and treatment of STIs</li> <li>Condom promotion and provision</li> <li>Identification and treatment of partners</li> <li>Counseling to promote risk reduction</li> </ul>	<ul style="list-style-type: none"> <li>Improve data collection and analysis by health workers</li> <li>Introduce an attractive STI packet to encourage partner notification and referral to clinics</li> <li>Implement IEC activities to encourage treatment seeking and partner referral</li> <li>Monitor numbers of STI patients and referrals seeking treatment</li> </ul>
<b>Target Group</b>	Multi-sector approach to HIV prevention targeting populations of under-served urban areas and migratory transit routes in seven countries	<ul style="list-style-type: none"> <li>Population of 210,000 in one rural district</li> <li>Staff of six public sector clinics in one rural district</li> </ul>	<ul style="list-style-type: none"> <li>Population of Maputo city</li> <li>All public sector health staff in Maputo</li> </ul>
<b>Cost of Kit</b>	A cost-recovery price was set for each kit; on average a 10% margin was added	Free public sector distribution	Free public sector distribution
<b>Implementation Design</b>	<ul style="list-style-type: none"> <li>Collaboration among various private, government, and NGO entities for a multi-sectoral approach to HIV prevention in seven countries</li> </ul> <p>Piloted seven PPST kits in Côte d'Ivoire</p> <ul style="list-style-type: none"> <li>Trained providers</li> <li>Ivoirian central pharmacy fabricated kits</li> <li>Health clinics/centers responsible for stocking supplies</li> <li>Prescription required</li> </ul>	<ul style="list-style-type: none"> <li>Collaboration among district MoH, researchers, and training institute</li> <li>Trained 16 nurses</li> <li>Introduced and evaluated six PPST kits</li> </ul>	<ul style="list-style-type: none"> <li>Trained staff of all 17 public sector health clinics</li> <li>MoH is responsible for maintaining the supply of STI medicines</li> <li>Prescription required</li> </ul>
<b>Evaluation Process</b>	Conducted mid-term internal evaluation	Operations research intervention	No formal evaluation; regular monitoring by social marketing staff
<b>Results</b>	<p>In Côte d'Ivoire</p> <ul style="list-style-type: none"> <li>Training of health care providers enabled more accurate diagnosis of STIs</li> <li>Frequent stock outages were experienced by central pharmacy</li> </ul>	<ul style="list-style-type: none"> <li>Prescription of proper drugs was 88% compared to 50% in non-intervention control site</li> <li>Adequate patient counseling, including for partner referral and condom use</li> <li>Providers had positive attitudes and respect for privacy</li> </ul>	Preliminary results indicate STI treatment is improving and condom use and partner referrals are increasing

## Key Program Components

**T**he lessons drawn from the Cameroon and Uganda social marketing projects, as supported by the other case studies, point to four essential elements that should be part of any PPST intervention, be it local or regional, using private, public, or NGO channels. A closer look at these four components—formative research; the TAC; provider training; and IEC, promotional activities, and advertising—will underscore their importance for health impact. PPST program steps will also be summarized before moving on to a discussion of costs.

### Formative Research

Before PPST kits were introduced in Cameroon and Uganda, studies were conducted to learn where men sought treatment, to determine what medication was given and at what price, and to understand any constraints to seeking effective treatment. Data were also gathered on drug availability in retail outlets and clinics, treatments most commonly prescribed, interactions between provider and client at time of purchase, and counseling provided regarding condom use and partner referral. The research methodologies used included focus-group discussions, structured interviews with questionnaires, in-depth interviews, and simulated client visits.

In Cameroon, research revealed that 43% of men with an STI had not consulted a trained health care provider, but had sought advice from friends or relatives, or had self-diagnosed the infection. MSTOP

project implementers also learned that STI treatment was not always standardized, complete, or correct. For example, as many as 80% of urethritis patients in Yaoundé were found to have received inappropriate treatment [20].

Studies confirmed that most Ugandans considered a drug shop to be a place where one could seek advice and treatment for a wide range of sicknesses, infections, or conditions. The client could purchase a variety of medicines, including antibiotics. A survey of practices revealed that drug shops and ordinary shops together provided 49% of all antibiotics, and that 62% of all antibiotics were dispensed from informal sources [1].

In Uganda, it was important to illustrate to the MoH and drug regulating authority the limitations of the status quo. Formative research revealed that men with urethritis tended to self-diagnose or seek treatment from drug shops because there were few pharmacies outside the capital city of Kampala. In addition, drug shops were less expensive and considered more confidential than private clinics.

Drug shop personnel often did not correctly diagnose infections, thereby prescribing incomplete or incorrect treatment. Due to their extreme discomfort, clients were known to pay as much as 15,000 Ugandan shillings (approximately \$10) for treatment of urethritis. Those who could not afford the full regime would purchase only partial treatment. These studies confirmed that few providers followed the MoH national guidelines on counseling, condom use, and female partner referral during treatment. The social marketing intervention was designed to address all these STI service shortfalls.

The studies in Uganda were conducted by independent research firms or private consultants, and were therefore considered objective and unbiased. As a result, government authorities were more willing to accept the findings than they would have been if the implementing organizations had designed and conducted the research. In the West Africa regional initiative and the public sector interventions, regular data collection to track adherence and partner referral relied on the participating health facilities.

### Research Essentials

**Through research that is objective and unbiased, find:**

- **Where men seek treatment for STIs.**
- **What medication people receive to treat STIs.**
- **What counseling or advice is provided at service-delivery points.**
- **How much people pay for treatment.**

## **Provider Training: An Example from Uganda**

In Uganda, the MoH adopted the policy of syndromic management for STIs and began training public sector staff in 1995. Many drug shop owners were former public sector employees and had received some training in the past. However, a training needs assessment conducted before pilot implementation revealed many of these service providers had inadequate knowledge in the areas of recognizing urethritis, recommending treatment in line with syndromic management, and giving instructions on issues including the complications of urethritis. The service providers also lacked risk-reduction knowledge and condom demonstration skills [3].

The broad objectives for the training were to equip service providers with adequate knowledge and skills to manage male urethritis using the PPST kits, and to promote kit acceptability as well as utilization. The provider training emphasized client education and counseling, confidentiality and professionalism [3]. Of over 1,000 Class C drug shops, pharmacies and private clinics assessed by project staff as potential outlets, 450 were selected for potential participation in the pilot phase. An external agency was contracted to conduct the training. It became evident during the training that staff of potential outlets possessed varying English literacy levels, requiring the trainer to quickly adapt the curriculum. By the end of the training, 250 providers had qualified to market Clear Seven. These providers illustrated, through a post-training test [2], that they could correctly:

- Deliver educational messages contained in the kits' informational inserts, fliers, and posters on management of urethritis in men.
- Apply professional ethics when handling patients with urethritis.
- Correctly diagnose, prescribe, and dispense a complete PPST kit for male urethritis.
- Refer female sexual partners, patients with other STIs, those not responding to Clear Seven, and those who could not afford the drugs to an appropriate health unit for further management.
- Apply social marketing techniques to promote effective sales of complete PPST kits for male urethritis.

**Promotional and advertising**

**activities were restricted in**

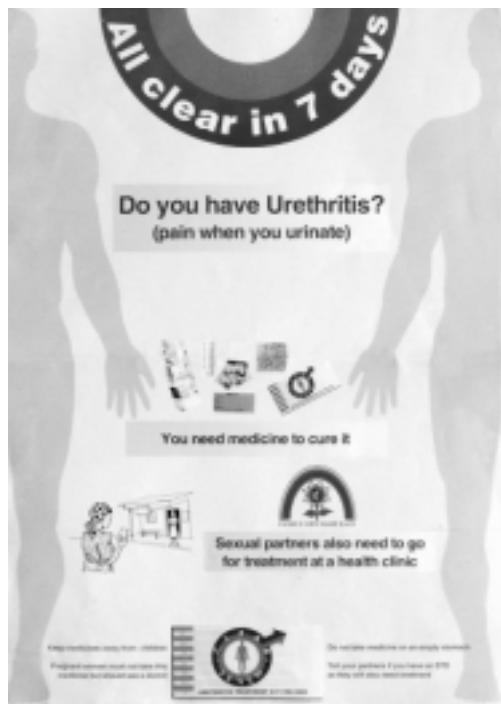
**both Uganda and Cameroon.**

**Because laws prohibited**

**mass media advertising of**

**brand-name drugs, alternative**

**methods were devised.**



Informational posters raise client awareness in drug shops and referral clinics.

### IEC, Promotional Activities, Advertising

All the PPST kits reviewed in this report included treatment instructions, educational information, condom use instructions, and partner referral cards. The development of any PPST kit's information and prevention materials should be done with the target audience in mind. Evaluation of the MSTOP informational brochure found it should have been written for a lower literacy level. In Uganda, therefore, product inserts were designed with the use of focus groups and were targeted at the audience in the pilot area

## The Technical Advisory Committee

It is essential to have a forum to ensure ownership and commitment by all key stakeholders. The TAC should meet regularly, but on an as-needed basis. For example, the TAC in Uganda was crucial in obtaining the necessary exemptions to distribute antibiotics OTC. This TAC met four times between its establishment in January 1998 and the end of the pilot phase in June 1999. A TAC can fulfill the following functions:

- 1 Provide technical support on policy issues regarding the PPST project.
- 2 Provide advocacy, including obtaining authorization from regulatory authorities.
- 3 Establish guidelines on regulatory framework and appropriate use of PPST kits by providers and consumers.
- 4 Foster close cooperation and collaboration among all stakeholders.
- 5 Review, approve, and provide direction on provider training program, treatment for female partners, and prevention of PPST kit misuse.
- 6 Provide overall direction on marketing of PPST kit, management and evaluation of PPST project.

using three local languages. In addition, posters and informational leaflets were freely distributed in the Uganda pilot communities.

Promotional and advertising activities were restricted in both Uganda and Cameroon. Because laws prohibited mass media advertising of brand-name drugs, alternative methods were devised. In Uganda, the Clear Seven project coordinator conducted a one-day workshop for the staff of the Capital Doctor radio program and submitted questions to be discussed during the weekly radio phone-in show. In this way, from March through June 1999, frequently asked questions

could be answered and other concerns discussed. Similarly, CMS utilized the "Dr. AMREF" (African Medical Research Foundation) newspaper column to discuss urethritis and the availability and uses of Clear Seven. Four articles were printed during the pilot phase. The Clear Seven project also utilized gatherings of young men in the target communities, such as factory workers, mechanics, market vendors, and at taxi stands, to teach them about urethritis and the availability of Clear Seven. Over 4,000 people were reached through such informal sessions. The product also benefited from word of mouth by those who had used or recently learned about Clear Seven.



# Program Steps for PPST Kits

These steps should be included in any PPST program, and are particularly important for social marketing kits.

## Design Stage: 1–2 Years

### Assess Need

- Priority health needs include STI prevention and treatment
- STI prevalence data show the common STIs to be among those a PPST intervention can address
- Documentation confirms sub-standard STI care that could be improved by kits

### Collect and Review Baseline Information

- Treatment-seeking behavior by men and women
- Barriers to seeking treatment
- Provider costs and consumer prices for various treatments
- General availability and price of antibiotics
- Knowledge-Attitudes-Practices (KAP) survey of men and women regarding STIs
- Pharmacy/drug shop distribution survey determining whether number and geographic distribution of providers is appropriate for where people seek treatment

### Analyze Policy and Regulatory Environment

- Government policy allows use of generics outside the public sector  
**If not:** name-brand drugs can be made affordable through social marketing  
**If not:** over-branding is allowed
- Authorization for OTC sale of antibiotics is probable

- If outside bulk purchase is needed, import restrictions are known
- MoH has policy on syndromic management for STIs, especially male urethritis, that covers diagnosis, treatment protocols, partner notification, health education, and condom provision  
**If so:** policy guidelines are comprehensive and easy to follow  
**If so:** drugs recommended for treatment are on MoH essential drug list  
**If not:** policies and guidelines can be developed

### Determine Most Effective, Feasible Intervention

- Identify Target Group
  - Solely men, or men and their female partners
  - Other key characteristics, including willingness and ability to pay, geographic location
- Determine Method of Diagnosis and Treatment
  - Syndromic management with or without lab facilities
  - Number of syndromes to be treated through PPST kits
  - Prescription requirements
  - Contents of PPST kit
- Determine Distribution System
  - Public hospitals, clinics and pharmacies
  - Private, NGO, and informal sector health care providers
  - Combination
- Determine Role of Social Marketing
  - Distribution: accessible outlets, consistent supply
  - Pricing Structure
  - IEC and Promotion

### Establish TAC

- Membership representative of key stakeholders

### Begin Brand and Logo Development

- Focus groups with target audiences conducted

### Obtain Authorization for OTC Sale of Antibiotics, If Necessary

## Planning & Implementation Stage: Length as Appropriate, 6–12 Months

- Providers and outlets selected
- Kit contents ordered, registered, and packaged
- Price structure and margins established
- Syndromic management training protocol for providers developed
- Provider monitoring and supervision plan implemented
- Outlet distribution plan to track sales and prevent stock outages established
- IEC and promotional strategy determined
- Success indicators specified
- System for ongoing data collection on these indicators established

### Evaluation: Immediately Following Implementation

- Independent evaluator identified
- Independent success-indicator data collected by evaluator
- Evaluation results used to improve and, if appropriate, to expand intervention

## Costs

**I**n general, the most significant considerations for any PPST intervention are sufficient funding and time for program development, advocacy, introduction, and evaluation. To give realistic estimates of the full costs for social marketing a PPST kit, a summary of retail prices and margins illustrated by examples from Cameroon and Uganda will lead into a detailing of Clear Seven pilot expenditures. Following these facts and figures, overall PPST program recommendations will be offered.

### Retail Prices and Margins

*There is no “rule of thumb” on how best to determine an affordable price for PPST kits. The following should be considered:*

- PPST kits should be affordable to the target audience.
- There may be pressure from the MoH or donors to recover the full cost of the kit. To keep the kit affordable, donor or government subsidization should be sought, at least for early phases of the project.
- Market research data are integral to successful price setting.
- Willingness to pay tends to be higher for curative treatments than for preventive care.

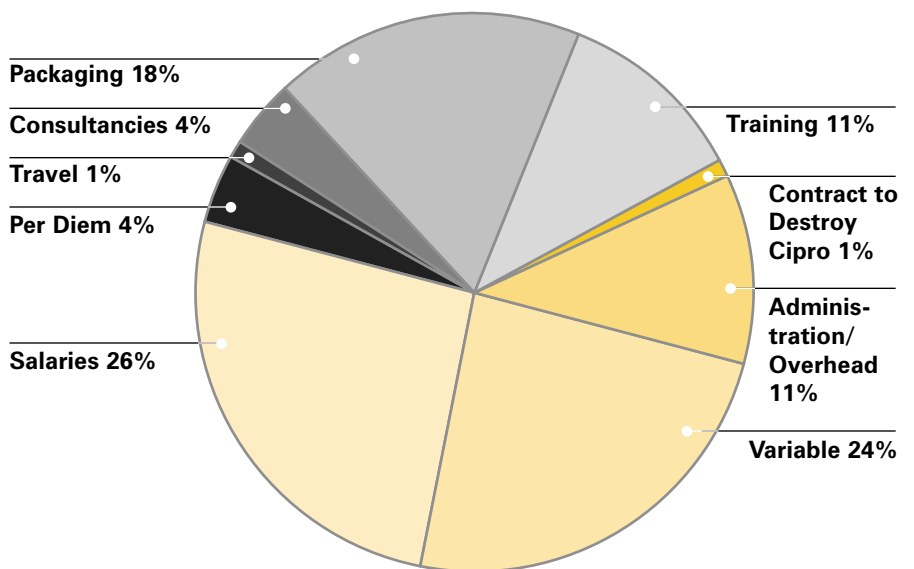
In Cameroon, for example, the MoH did not want the PPST kit to be subsidized, but rather, priced to cover the cost of the contents with a view to financial sustainability. Willingness-to-pay studies revealed that to treat urethritis, people were paying the equivalent of \$15 to \$27

in pharmacies, and up to \$36 in private clinics; laboratory tests could add an additional \$36. Despite the fact that the drugs were provided at a preferential price by a pharmaceutical company, the total cost for the kit was equivalent to \$16.67. This consumer price included the purchase price of the drugs from the private distributors (\$10), which was comparable to the amount paid by clients in private pharmacies. This price, although within the range of what people were willing to pay, was prohibitively high for the target audience and contributed to lower-than-expected sales.

Conversely, in Uganda, the suggested retail price of \$1.33 was easily

affordable for the target audience. The drugs—generics provided through the World Bank-sponsored STI Project—were considerably less expensive than the brand names purchased for the Cameroon MSTOP Project. In Uganda, providers purchased Clear Seven at \$.67 and sold it for \$1.33, a 100% profit. However, because the volume sold by each outlet was low, there was not much income to be made from the product. Cannibalization of the kits to resell the drugs did not occur, as had been feared by the NDA, because doxycycline was already readily available in the market at a relatively low price, and one tablet of ciprofloxacin was not considered sufficiently valuable for destruction

### Line Item Expenditures During Uganda Pilot







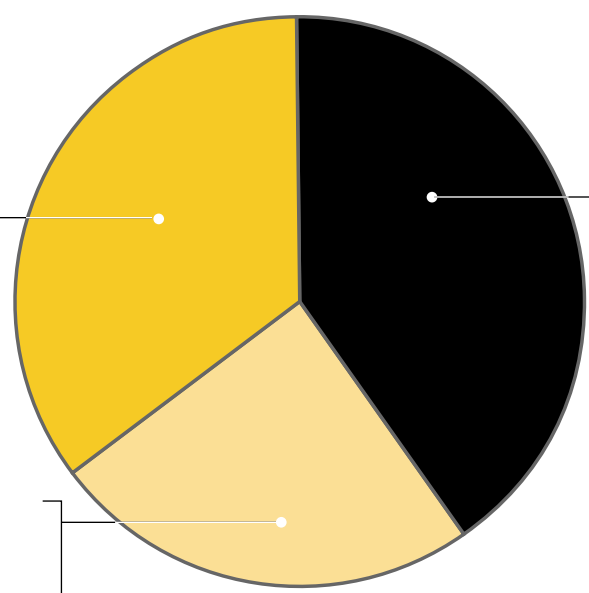
## Total Expenditures During Uganda Pilot

### Semi-Fixed Costs - 35.3%

- salaries
- training
- local travel, per diem
- consultative meetings with key stakeholders
- identification of outlets, providers
- monitoring and supervision
- distribution and retrieval of expiring kits

### Variable Costs - 24.0%

- outer packaging/boxes
- blister-pack trays
- printing of inserts, referral cards, and stickers
- condoms
- drugs – doxycycline and ciprofloxacin
- packing labor and foil
- promotional items, advertising



### Fixed Costs - 40.7%

- development of brand name, logo, and kit design
- design and translation of instructional/educational insert
- blister-packaging machine for packaging company
- research<sup>7</sup> and evaluation
- product recall and destruction of expired product
- contribution to administrative expenses and overhead

**Total expenditures for the pilot phase:**  
Ush 814,127,440 or \$563,020.

**Cost per kit produced:**  
Ush 4,122 or \$2.75 for 197,494 kits

of the kit. The final evaluation showed that some providers sold the kit for as much as \$2—higher than suggested retail, but still affordable to the target audience. This price structure is currently being reviewed to improve cost recovery and create incentives for retailers to promote and distribute Clear Seven.

### Pilot Phase Expenditures

#### The Example of Clear Seven

Based on the interventions reviewed in this report, an estimated \$500,000

is needed to design, implement, monitor and evaluate a pilot PPST kit for gonorrhea and chlamydial infection, with primarily private sector distribution. The example of Clear Seven is provided in some detail to present realistic estimates of the full costs for social marketing a PPST kit. In hindsight, the procurement of 200,000 kits for a limited pilot (fewer than 350 providers in parts of four districts) was overambitious. Sales of Clear Seven were improving steadily as demand increased, primarily through word of mouth, but the expiration date for the drugs became

pending. The number of kits ordered should be appropriate for the size of the target population.

*Total Clear Seven pilot expenditures are broken down into three categories:*

- Fixed costs—required regardless of how many Clear Seven kits were produced, distributed, or sold
- Variable costs—fully dependent on how many kits were produced
- Semi-fixed costs—minimum expenditures were made but total expenditures depended on how many kits were produced.

<sup>7</sup> Does not include independent treatment-seeking research and drug shop surveys conducted by other entities.

## Recommendations

**T**he private sector model currently being promoted in Uganda best lends itself to the social marketing methodology. Through social marketing, treatment for gonorrhea and chlamydial infection is



Social marketing makes high-quality, affordable health products, services, and information available in convenient places, like this neighborhood shop in Uganda.

being made more accessible, available, affordable, and attractive to the people who need it. The Uganda design aims to have as many providers dispensing the PPST kit as can be trained in the syndromic management of these two STIs, supplied with kits, and carefully monitored to ensure quality services. The intervention also includes identification and training of the private sector providers most frequented by men in the target group. Regardless of whether PPST kits are distributed through the public or private sector, experience to date has confirmed several conditions in particular that enable program success. Although the following list was developed based on lessons from various countries, interven-

tions should be tailored to meet country-specific needs.

1. Independent research to provide rationale and objective platform for negotiations with host government.
2. Appropriate and adequate health care provider training in syndromic management, use of PPST kits and client counseling to ensure motivation of staff and quality of services.
3. Ongoing field-level training and supervision matched by advocacy (possibly through TAC) at central agencies, particularly MoH, to sustain ongoing use of proper protocols.
4. Close monitoring and supervision of sales and use of PPST kits, including affordability for target audience.
5. Adequate distribution and logistics system to avoid stock outages, especially with numerous outlets.
6. Community participation and demand-creation activities to stimulate use of STI services and effectively deliver IEC.
7. Capacity building in planning and management to improve procurement, distribution, and use of essential drugs.

### Key Questions

**If you are considering a PPST intervention, you need to be able to answer yes to the following questions:**

**Do you know the prevalence of various STIs? of gonorrhea and chlamydial infection?**

**Is there a national STI syndromic management policy, including STI treatment protocols, accepted by all medical professionals and included in pre-service training and retraining curricula?**

**Do you know where men and women seek STI treatment?**

**Do you know how much people pay for treatment?**

**Do you know what barriers exist to obtaining proper diagnosis and treatment?**

**Do you have sufficient information regarding antibiotic resistance and strain diversity?**

**Can generic drugs be sold in the private/commercial sector?**

**Is sufficient funding available (up to \$500,000) to introduce and evaluate the intervention?**

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