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Control *of* Sexually Transmitted Diseases

A HANDBOOK FOR THE DESIGN AND MANAGEMENT OF PROGRAMS

AIDSCAP

USAID

AIDSCAP/Family Health International

Control *of* Sexually Transmitted Diseases

A HANDBOOK FOR THE DESIGN AND MANAGEMENT OF PROGRAMS

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PREFACE

The control of sexually transmitted diseases (STDs) is critical to the global improvement of the reproductive health of all people. The serious impact of STDs on women and children in particular, and the linkage between STD and HIV prevention are of profound concern to public health professionals worldwide.

Indeed, several studies have now validated the important role that STDs play in the spread of HIV, as well as the impact of STD treatment in HIV prevention. I believe that the lessons learned should now be applied globally.

Although various types of preventive behavioral interventions need to be greatly expanded, and work has to continue on challenging and important issues such as AIDS vaccines and drugs for those who are HIV-infected, STDs provide an available target of opportunity. There is already advanced knowledge about treatment and prevention, and success in this area is limited more by service issues than by a lack of scientific understanding. Better STD services also will mean improvements in reproductive health, including HIV prevention. Therefore, public health program managers and clinicians must seize on this without delay.

The publication of this book, *Control of Sexually Transmitted Diseases: A Handbook for the Design and Management of Programs,* is timely. It grew out of the recognition that STD control programs are multifaceted, and that managers should be well versed in all aspects of programming. Unlike most other books about STDs, this one provides a comprehensive account of STD management and prevention. It addresses the full spectrum of issues that STD managers at the national and local levels must consider when designing and implementing STD programs.

The handbook is not intended to be a clinical text, even though it contains technical material. Rather, for the people who design and/or manage STD programs, it provides an overview of the topics most salient to their programs. These include training, surveillance, curative and preventive services, evaluation and more.

Developed primarily for managers in resource-poor settings, the book starts with the assumption that health care providers in most societies operate under financial constraints. Often, this has meant that STD control efforts are seriously compromised.

The publication also should prove valuable to others who have an investment in STD control—family planners, child survival workers, donor groups and the like.

It is my hope that the use of the handbook will lead to an improvement in funding decisions, training, service design and delivery, and community education. This will lead to gains in STD and HIV prevention and care worldwide, and contribute to the ultimate goal of high-level reproductive health for women, men and children.

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INTRODUCTION

STD Control: A Public Health Priority

During the 20th century, improvements in sanitation and hygiene, reduced crowding, and the development of antimicrobials and vaccines have greatly reduced infectious disease morbidity in industrialized countries. In developing countries, smallpox has been eradicated, polio eliminated from the Western Hemisphere, and child survival prolonged through the expanded use of childhood vaccines, and improved management of diarrheal and acute respiratory infections of children. However, there is growing concern about the persistence, emergence or reemergence of a host of other infectious disease threats. Sexually transmitted infections, including HIV, figure prominently among these emerging infectious diseases. The number of microbial pathogens identified as causes of STD, and the morbidity attributable to STD, relative to that caused by other infectious diseases, have continued to increase throughout the 20th century. In fact, recent analyses show that STDs collectively rank among the five most important causes of years of healthy productive life lost [1,2] in developing countries.

Changes in human behavior and ecology, including socioeconomic factors and related economic development policies, the population explosion and the demographic transition (with rapid increases in the number of adolescents and young adults), rural-to-urban migration, war and attendant sociocultural disruption all have led to epidemic increases in STDs.[3] Sexually transmitted pathogens are increasingly being linked to various common disease syndromes and new sexually transmitted pathogens (such as HIV) are emerging, causing new sexually transmitted diseases (like AIDS). Unrestrained population growth and urbanization leave every reason to expect the continued emergence of new STD pathogens and syndromes into the next century. In addition, improved diagnostic methods have led to the identification of previously unrecognized pathogens (e.g., human T lymphotrophic virus [HTLV], and a growing number of human papilloma viruses [HPV]). Careful clinical epidemiologic studies have demonstrated that these pathogens are sexually transmitted and associated with diseases that were formerly considered idiopathic (e.g., tropical spastic paraparesis caused by HTLV, genital cancers caused by HPV).

Tables 1 and 2 provide current lists of sexually transmitted pathogens and associated sexually transmitted diseases and STD syndromes.[4] These can generally be divided into STDs that are curable (e.g., gonorrhea, chlamydial infection, syphilis, chancroid, donovanosis, trichomoniasis, and related syndromes), and those that are not yet curable (i.e., all viral STDs, including HIV/AIDS). This STD handbook details current strategies for preventing of both the curable and incurable STDs through behavior change *(see Chapters 4 and 10)* and the use of condoms *(see Chapter 5)*, and presents practical and innovative strategies for early detection and treatment of the curable STDs *(see Chapters 8, 9 and 13)*.

Table 1

SEXUALLY TRANSMITTED PATHOGENS

TRANSMITTED IN ADULTS PREDOMINANTLY BY SEXUAL INTERCOURSE		
Neisseria gonorrhoeae	Human immunodeficiency viruses (HIV-1 and -2)	*Trichomonas vaginalis*
Chlamydia trachomatis	Human T lymphotropic virus type I (HTLV-1)	*Phthirus pubis*
Treponema pallidum	Herpes simplex virus type 2 (HSV-2)	
Calymmatobacterium granulomatis	Human papillomavirus (multiple types)	
	Hepatitis B virus†	
Ureaplasma urealyticim	Cytomegalovirus	
	Molluscum contagiosum virus	
SEXUAL TRANSMISSION REPEATEDLY DESCRIBED BUT NOT WELL DEFINED OR NOT THE PREDOMINANT MODE		
Mycoplasma hominis	Human T lymphotrophic virus type II (HTLV-II)	*Candida albicans*
Gardnerella vaginalis and other vaginal bacteria	(?) Hepatitis C virus	*Sarcoptes scabiei*
	Herpes simplex virus type 1 (HSV-1)	
Group B streptococcus	Human herpes virus type 8 (Kaposi's sarcoma-associated)	
	(?) Epstein-Barr virus (EBV)	
TRANSMITTED BY SEXUAL CONTACT INVOLVING ORAL-FECAL EXPOSURE		
Shigella spp.	Hepatitis A virus	*Giardia lamblia*
Campylobacter spp.	*Entamoeba histolytica*	

* *Includes protozoa, ectoparasites, and fungi*
† *the relative importance of sexual and parenteral transmission among adults varies in different settings*

Table 2
COMMON STD SYNDROMES AND ETIOLOGIC AGENTS

Urethritis: males	*N. gonorrhoeae, C. trachomatis, U. urealyticum, T. vaginalis,* HSV
Epididymitis	*C. trachomatis, N. gonorrhoeae*
Mucopurulent cervicitis	*C. trachomatis, N. gonorrhoeae*
Vulvovaginitis	*C. albicans, T. vaginalis*
Bacterial vaginosis (BV)	BV-associated bacteria
Acute pelvic inflammatory disease	*N. gonorrhoeae, C. trachomatis,* BV-associated bacteria
Ulcerative lesions of the genitalia	HSV-2, HSV-1, *T. pallidum, H. ducreyi, C. trachomatis* (LGV strains), *C. granulomatis*
Genital and anal warts	Human papillomavirus (genital types)
AIDS	HIV-1, HIV-2; also many opportunistic pathogens
Viral hepatitis	HBV
Neoplasias	
Squamous cell cancer of the cervix, anus, vulva,, vagina, or penis	Human papillomavirus (especially types 16, 18, 31, 45)
Kaposi's sarcoma	Human herpes virus 8 (?)
Lymphoid neoplasia	HIV, EBV, HTLV-1
Hepatocellular carcinoma	HBV
Tropical spastic paraparesis	HTLV-1
Scabies	*S. scabiei*
Pubic lice	*P. pubis*

Abbreviations: HSV= herpes simplex virus; EBV=Epstein-Barr virus; HBV=hepatitis B virus

WHY AGGRESSIVE STD CONTROL EFFORTS ARE NECESSARY

The World Health Organization estimates that the global incidence in 1995 of new cases of selected curable STDs—gonorrhea, chlamydial infection, syphilis and trichomoniasis—was 333 million.[5] The global prevalence of active or latent infection with the common chronic viral STDs such as genital herpes simplex virus, genital HPV, hepatitis B virus and, increasingly, HIV, could be estimated in the billions of cases, since in some populations the majority of adults become infected with one or more of these pathogens. The consequences of being infected with an STD can be divided into two categories: complications and sequelae seen in STDs other than HIV/AIDS, and those directly related to HIV/AIDS. Social and economic consequences of these conditions as well as the direct health costs need to be considered. The most serious health consequences of STDs, other than HIV/AIDS, tend to occur in women and newborn children. Complications in women include cervical cancer, pelvic inflammatory disease with resulting infertility, chronic pain, ectopic pregnancy and related maternal mortality. In developing countries maternal complications directly related to untreated STDs are a major cause of infant and maternal morbidity and mortality. Complications in newborns include con-

genital syphilis, gonococcal infection of the conjunctivae—a potentially blinding condition—and perinatal hepatitis B infection. Measures for preventing these three manifestations of STD in newborns have been judged among the most cost effective measures for preventing neonatal infectious morbidity *(see Chapter 9)*.[6]

A remarkably large and growing number of malignancies is now partially attributed to pathogens that can be sexually transmitted. These malignancies include cervical cancer and hepatocellular carcinoma, two of the most common malignancies in developing countries; squamous epithelial cell cancers of the vagina, vulva, penis, and anus; Kaposi's sarcoma; and T lymphocyte malignancies. Serious neurologic diseases caused by STD pathogens include those attributable to syphilis, as well as neonatal herpes encephalitis, tropical spastic paraparesis/HTLV-I-associated myelopathy, and various HIV-associated neurological disorders. Thus, effective prevention and control of STDs is now recognized as (1) a high priority for preserving reproductive health, especially among women; (2) an important approach to preventing cancer and neurologic disease; and (3) a very cost-effective approach to preventing neonatal morbidity. Nonetheless, public awareness of the spectrum of adverse health consequences of sexually transmitted infections has been slow to develop—perhaps because the link between infection and consequences is obscured by the frequently subclinical nature of early infection, especially in women. Other reasons include the long delay until recognition of adverse reproductive health consequences or the occurrence of malignancy or neurologic sequelae. And, finally, there has not been a major effort to educate the public on the potentially serious effects of sexually transmitted infections.

The Role of STDs in Increasing Sexual Transmission of HIV

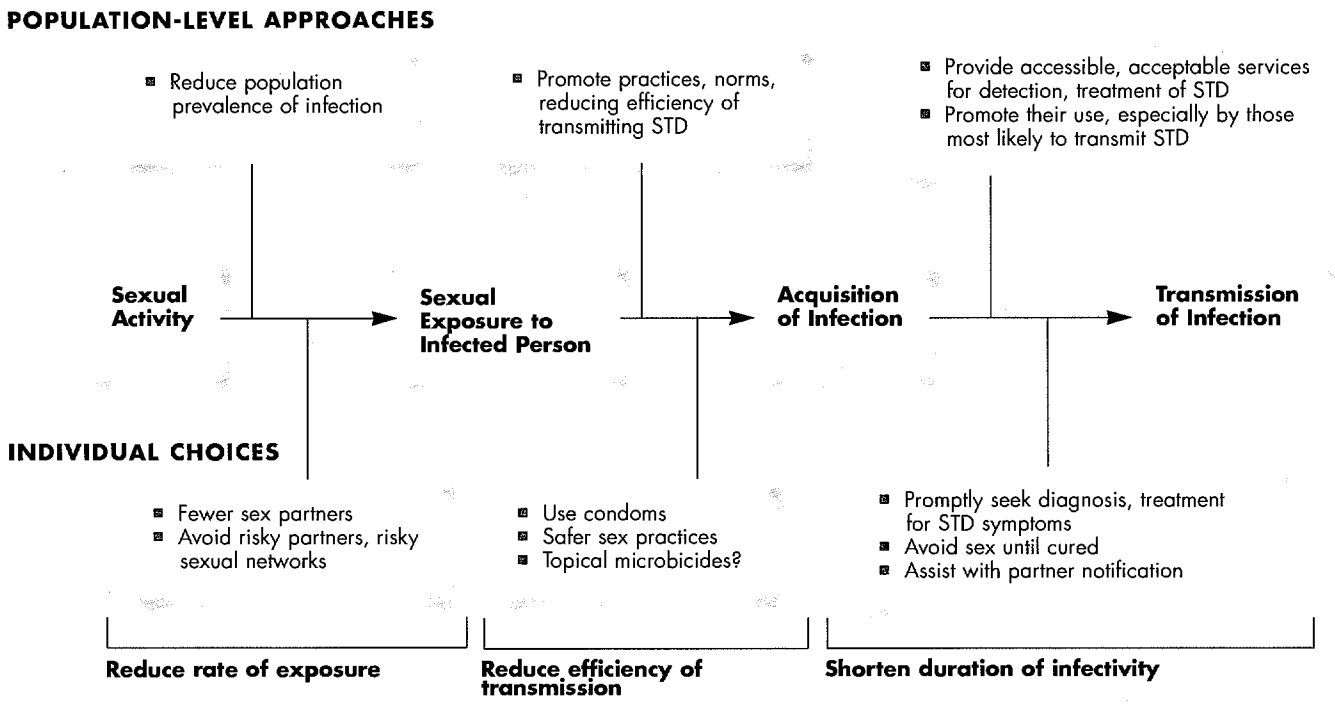
The impact of other STDs on sexual transmission of HIV was initially suspected on the basis of epidemiologic studies, showing that persons with an ulcerative or nonulcerative STD appear more susceptible to acquiring HIV infection. Subsequent studies showed that urethral and endocervical inflammation caused by non-ulcerative STDs increases genital shedding of HIV-infected cells, and thus probably increases infectivity of the person with HIV infection.[7,8] The importance of STD in promoting HIV transmission and the potential effectiveness of STD control in preventing sexual transmission of HIV were confirmed in Mwanza, Tanzania, where a community randomization trial of strengthened syndromic management of STD was associated with a 42 percent reduction in HIV incidence over a two-year period.[9] Thus, strengthened STD prevention and management have become essential components of HIV prevention programs.

How STD Epidemiology Defines the Basic Strategies for Preventive Intervention

The rate of spread of STDs, including HIV, is determined by three factors: (1) the average rate of exposure of susceptible people to infected people; (2) the average probability that an exposed susceptible person will acquire the infection (the "mean efficiency of transmission"); and (3) the average time that newly-infected persons remain infectious and able to continue spreading infection.

Anderson and May [10] have expressed these relationships in a mathematical model, in which R_0, the reproductive rate of infection, represents the number of secondary cases of STD arising from a new case. In this model, $R_0 = c \times ß \times D$, where c is the "effective mean rate of sexual partner change" within the population, ß is the mean efficiency of transmission per exposure, and D is the mean duration of infectiousness after acquisition of a new infection. Thus, interventions can prevent spread of an STD within a population by (1) reducing the rate of exposure to STD by lowering the rate of partner change; (2) by reducing the efficiency of transmission; or (3) by shortening the duration of infectiousness for that STD. Figure 1 presents a simple conceptual approach to STD prevention, illustrating these three primary targets of various individual and population-level interventions. For HIV infection and most other viral STDs, therapy has not yet been clearly

Figure 1
INDIVIDUAL AND POPULATION-LEVEL APPROACHES TO STD PREVENTION



shown to shorten the duration of infectiousness, so interventions currently target the rate of exposure and the efficiency of transmission. For the curable STD, interventions also target the duration of infectiousness.

"BEHAVIORAL" VS. "BIOMEDICAL" APPROACHES TO STD PREVENTION

The above discussion and Figure 1 make clear that the distinction between "behavioral" and "biomedical" interventions for STD prevention is artificial, since both behavioral and biomedical approaches are often required, whether the objective is preventing exposure, preventing acquisition, or preventing transmission of STD. In fact, behavioral and biomedical approaches are complementary, and interdisciplinary approaches will be essential in the future. Biomedical interventions may be ineffective without behavioral components to support them; and, behavioral approaches must address all of the factors responsible for sustaining transmission of infection.

It is not reasonable to focus solely on preventing exposure, or acquisition, or transmission. While it is true that reduction of exposure, efficiency of transmission, or duration of infectiousness to zero would eliminate transmission altogether, these are not realistic goals. Focusing on one goal, to the exclusion of the others, would have diminishing returns. Conversely, equal allocation of resources to each of these three targets is neither feasible in every setting, nor necessarily the most cost-effective approach even when feasible. Nonetheless, a balanced effort initially seems desirable, in which resources are increasingly committed to each potential point of intervention, as the marginal yield of increasing efforts in each area is monitored.

To reduce exposure to STD, behavioral interventions can be designed to delay the onset of sexual activity among youth, to decrease rates of new sex partner

acquisition, to encourage choice of a safe sexual partner, and to foster faithful monogamy or polygamy. In addition, a lower prevalence of STD in the population will lower the risk that a sexually active individual will be exposed to an STD.

To reduce the efficiency of STD transmission per sexual exposure to infection, behavioral and biomedical interventions can include promoting a delay in the sexual debut of females (young women are anatomically more susceptible than older women to acquiring certain endocervical infections if they are exposed), safer sexual practices, use of condoms, use of topical microbicides and immunization (however, currently the only available vaccine against an STD is hepatitis B vaccine) should be promoted.

Finally, **to reduce the duration of infectiousness** accessible, acceptable and effective services for early STD detection and treatment are necessary together with promotion of their use when they are needed.

Thus, each step in the intervention pathway, from avoiding exposure, to preventing acquisition of infection, to preventing further transmission of infection, involves both behavioral and biomedical interventions. A coordination of such interventions is essential.

It is important to emphasize that interventions that reduce risky sexual behaviors or result in increased condom use, can prevent most, if not all, important STDs; whereas those designed to improve only early detection and curative treatment of STDs can reduce transmission only of those specific diseases that are cured or suppressed.

Unique Issues in STD Prevention

Unique aspects of the epidemiology of communicable diseases have important implications for STD prevention. Patterns of intimate contact between members of the population generally do not directly determine the incidence of non-communicable diseases, but they do directly determine the incidence of communicable diseases. Roy Anderson and his colleagues at Oxford have demonstrated how the variance in rates of partner change within the population greatly influence the rates of spread of STD.[11] Those individuals with highest rates of partner change, the so called "core groups," disproportionately increase the rate of spread of STD within a population. Research on sexual behavior mixing becomes critical in order to determine the identity and priority of various possible "core groups." Further, it can be shown by mathematical models that patterns of sexual partner mixing, and the characteristics of sexual networks, are important determinants of the rates of spread of STD.[12, 13] For example, if those with many partners tend to have sex with others who have many partners ("assortative mixing"), infection spreads rapidly at first; and infection spreads fastest within "dense" sexual networks, which have sexual links between many people over a short period of time. **Thus, interventions should have greatest impact if they are effectively focused and delivered among individuals who have many partners, and in dense sexual networks** *(see Chapter 13).* To the extent that interventions provided through the private or public health-care sectors do not reach such populations, the impact on STD spread in the population may be quite limited.

Finally, for communicable diseases in general, and for STD in particular, there is a threshold rate of transmission required to sustain spread of an infection in the population. For STD, when the reproductive rate of infection is greater than one ($R_0 > 1$), more than one secondary case on average arises from each new case, and the infection spreads. Whereas when the reproductive rate of infection remains less than one ($R_0 < 1$), the infection eventually disappears from the population. As a result, when the value of R_0 is 1 or more, then interventions that reduce the value of R_0 to less than 1, if sustained, could drive the infection to extinction in the entire population. This is true even when these interventions are provided only to those individuals and networks that experience highest rates of transmission. For example, this could explain how a modest reduction in STD incidence or prevalence in the Mwanza, Tanzania trial of STD syndromic management could have led to a 42 percent reduction in sexual transmission of HIV.

For communicable diseases, curative treatment provides secondary prevention at the individual level, and primary prevention at the population level. In public health, it is customary to distinguish between primary and secondary levels of prevention. A leading textbook on public health and preventive medicine[14] states that "in epidemiologic terms, the aim of primary prevention is to reduce the *incidence* of disease and injury...by removing the precipitating causes and determinants of departures from good health;" whereas, "the aim of secondary prevention is to detect and correct departures from good health as early as possible; in other words, to reduce the *prevalence* of disease and disability." Although these distinctions apply well to the noncommunicable diseases, like hypertension and trauma, the distinctions become blurred for the curable communicable diseases, for which early detection and treatment reduce the infectivity duration, and thus lower the incidence of infection. Thus, for the bacterial STDs, which are communicable from person-to-person, early detection and curative treatment of recently infected individuals provide *secondary prevention at the individual level* by preventing complications in the individual; and provide *primary prevention at the population level* by preventing further transmission. Thus, the terms "primary" and "secondary" prevention, when applied to STD prevention, are better replaced by terms more specifically descriptive of the intervention used when applied to STD prevention.

Even when applied to the chronic incurable viral STDs, such as HIV infection, for which the duration of infectivity may or may not be influenced by antiviral therapy, use of the terms "primary" and "secondary" prevention may mislead. When "primary prevention" refers to preventing *acquisition* of infection, interventions focus on uninfected persons; whereas when primary prevention also encompasses prevention of *transmission* of infection from those already infected, interventions also can focus on those who are already infected. In research and public health programs on prevention of curable and incurable STDs, both behavioral and biomedical scientists have tended to underemphasize the importance of preventing the transmission of infection from those who are already infected.

On the Importance and Use of this Handbook for STD Control

This handbook has been designed to fill an important unmet need in the field of STD prevention and control. Existing texts address in detail the etiology, epidemiology, pathogenesis, clinical manifestations, diagnosis and treatment of STDs, but none provides a comprehensive and integrated approach to the design and management of STD control programs, particularly for resource-limited settings.[15,16] This has been a glaring deficiency in the field. Many of the essential technical tools for STD prevention and control are now in hand, but what has been lacking are pragmatic guidelines for the effective use of these tools in an integrated program. Such a guide has been long overdue, and this handbook should now prove the catalyst to finally begin mobilizing technically sound programs in developing countries in an effective way. It will complement existing textbooks for STD management in industrialized countries as well.

The handbook is for STD program managers and for all levels of service providers. It includes sections covering program management issues *(Chapters 2, 3, 6, 7, 14, 15);* case management issues *(Chapters 8, 9, 11, 12);* other service issues *(Chapters 4, 5, 10);* and innovative approaches suggested by authors who have a wealth of experience in STD program development *(Chapter 13).* Thus, health managers, including categorical STD program managers and primary health-care managers, will find the book an essential training, planning and management tool. Service providers will find practical and up-to-date guidelines for preventive and clinical services. The book's chapters are autonomous and modular, with extensive cross-referencing to other chapters throughout the book.

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CHAPTER 1

STDs: Global Burden and Challenges for Control

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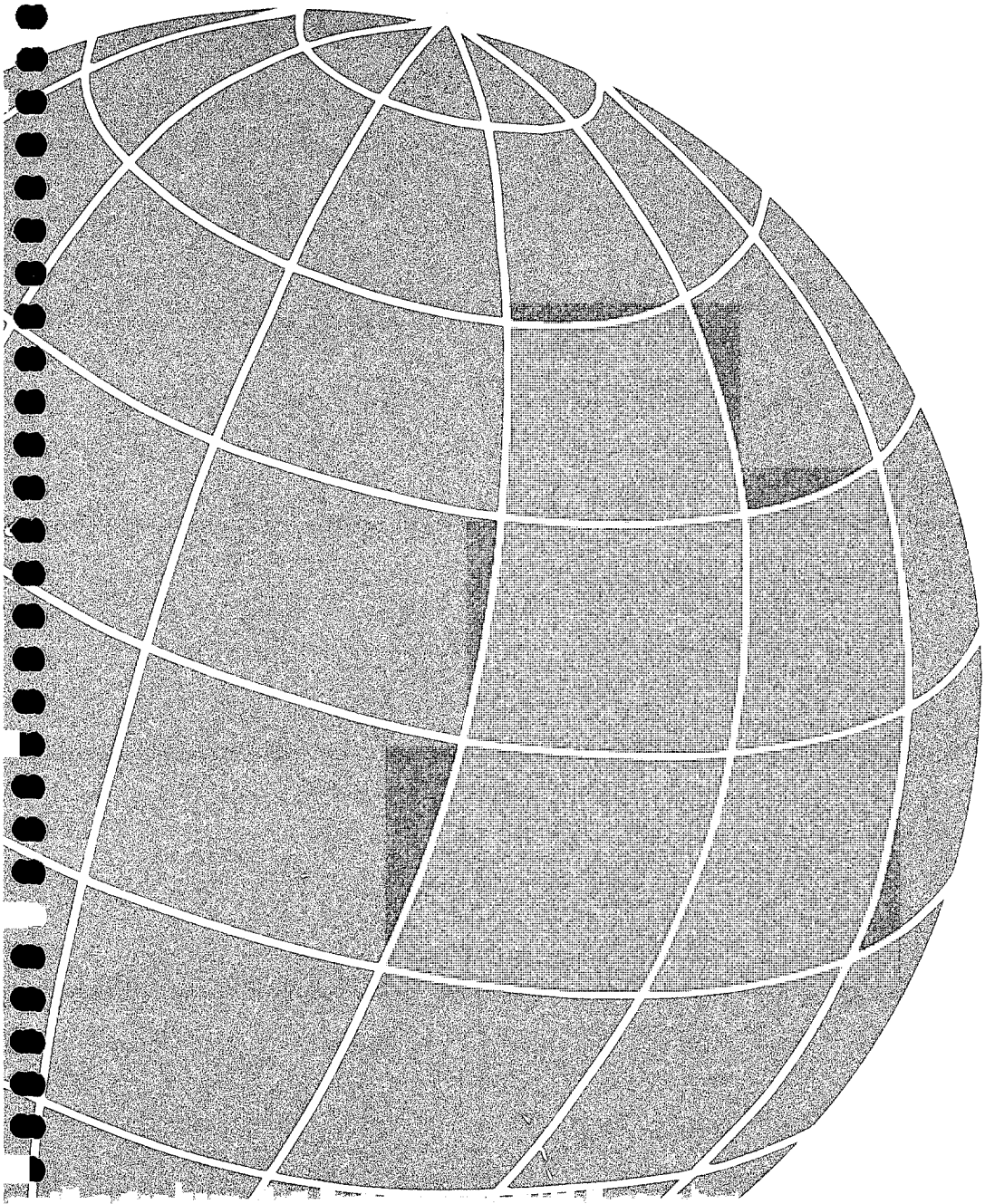


preview CHAPTER 1

STDs: Global Burden and Challenges for Control

INTRODUCTION

This chapter provides an overview of the STD epidemic's epidemiology, the STD relationship to HIV, the socioeconomic consequences, and ways to mitigate the impact.

THE STD EPIDEMIC

MAGNITUDE

STDs rank in the top five disease categories for which adults in developing countries seek health-care services, with sub-Saharan Africa carrying the largest burden. Globally, approximately 333 million new cases of curable STDs occur each year.

DETERMINANTS OF STD EPIDEMIOLOGY

Determinants can be categorized as the physiological microenvironment, the behavioral/personal environment and the sociocultural macroenvironment. *(See Table 3 for examples).*

STD CONSEQUENCES: HEALTH, SOCIAL AND ECONOMIC

In women between 15 and 44 years of age, the morbidity and mortality due to STDs, excluding HIV, are second only to maternal causes. Socially, STD consequences such as infertility can lead to abusive behavior, divorce and commercial sex. Economically, the cost of diagnostics can exceed the per capita national healthcare budgets of many low-income countries.

THE CHALLENGES OF STD CONTROL

STD control depends on a synergistic relationship between numerous elements which, when combined with improved clinical case management, hold out the promise of a highly effective approach.

- **Behavior change,** key to STD prevention, is the end result of health messages that have been absorbed by community members through mass media and interpersonal strategies.
- **Health-seeking behavior** is both a function of attitudes toward disease and sex, and the accessibility and quality of healthcare facilities that deal with STDs.
- **Condom promotion** requires good quality and affordable condoms as well as community support for condom use.

- The **syndromic approach** to STD management is pragmatic in that it does not require lab facilities, and, patients are treated when they come in so they are not lost to follow-up.
- Effective, available and affordable **drugs** are a major condition for successful STD management.
- Often **partner management,** an STD case management cornerstone, is not implemented fully because of the social stigma and the lack of established systems.
- **Screening** asymptomatic individuals, especially women, is limited by the unavailability of inexpensive, accurate and rapid diagnostics.
- Because **core groups** are disproportionately infected with STDs, special efforts should be directed toward them.
- Good STD **management** involves a clear delineation of staff responsibilities and ongoing staff training as well as coordination with related programs.
- **Training** and updating providers in the syndromic approach to STD case management gives them a strategy that is efficient and respectful of patients.
- **Laboratories** play an essential role in epidemiological and microbiological surveys, antimicrobial susceptibility studies and in the validation of treatment and management approaches.
- **Surveillance, and monitoring and evaluation** are the basis for sustaining an STD case management program and keeping it relevant and effective.
- **Research**—epidemiological, behavioral and operational—is needed for planning and revising STD case management programs.

THE POLICY ENVIRONMENT

Managers can advocate for policy changes that can improve a country's capacity to deal with STDs. Areas for review include resources, restrictive provisions and access to services.

CONCLUSION

Managers must work internally and externally to build the appropriate infrastructures and coalitions needed for halting the destructive effects of STDs.

INTRODUCTION

Although sexually transmitted diseases (STDs) have been causing significant morbidity and mortality for years, it is only with the advent of the human immunodeficiency virus (HIV) that STD control is now receiving higher priority in both developed and developing countries. This is because STDs increase the transmission of HIV and have similar behavioral risk factors.[1,2] Globally, it is estimated that as many as 333 million new cases of curable STDs occur each year.[1] The indisputable facts that STDs produce serious economic, social and health consequences, made more clear by their association with HIV, and that all STDs are preventable and many are curable, make it incumbent on governments, communities and donors to meet the challenge of STD prevention and control.

Modeling the dynamic effect of STD prevention or cure on subsequent HIV and STD rates illustrates a dramatic effect. By curing or preventing one hundred cases of syphilis among an STD high-risk (core) group, approximately 109 new HIV infections and 4,132 new syphilis cases could be prevented in the next ten years.[3] The prospect that the consequences of STDs, including HIV infection, can be prevented, is a hopeful one.

> "It is truly remarkable that this high rank [of STDs] in terms of both burden and potential health gain is not reflected in higher specific expenditure for the control of HIV infection and CSTDs (classic STDs). Neglected training, poor diagnostic and therapeutic capabilities, high rates of quasi-irreversible sequelae and insufficient research and development efforts (at least for classic STDs) are all symptoms of this inadequate response."[3]

This chapter explores the epidemiology of STDs, and the epidemic's health and socioeconomic consequences in developing countries. It also looks at the challenges which, if met, could mitigate the impact of STDs.

The challenges are considerable. In many countries, the health-care systems are already strained dealing with other health problems. STDs, as they are classically diagnosed and treated, demand a level of provider time and diagnostic facilities that many countries do not possess. The stigma associated with STDs, the limited resources and limited access to suitable health care for those most at risk (women and youth), and the lack of affordable and effective drugs are just some of the constraints to STD control. There are also constraints within countries served by STD programs. For example, many beliefs and practices about STDs interfere with effective treatment.

This chapter sets the stage for the other chapters in this book. They address the role of STD managers in STD prevention and control through strategies such as behavior change, condom promotion and syndromic management. STD program managers have an enormous opportunity to significantly improve the health of the populations they serve. STDs pose a worthy focus for national-level efforts. There is support in the literature for and a growing global awareness of the importance of STD prevention and potential for STD control. Indeed, if progress can be made in decreasing STDs worldwide, significant decreases in HIV infections and maternal and infant morbidity and mortality will follow.

THE STD-HIV RELATIONSHIP

Numerous epidemiologic and biologic studies now support the fact that STDs, both ulcerative and non-ulcerative, enhance HIV transmission.[4] In addition, it appears that HIV alters the natural history of some STDs.[5] HIV has been identified in the genital tract of both males and females and found to be both cell-associated and cell-free.[6] HIV has also been isolated from the exudates of both male and female genital ulcers.[7, 8] The shedding of HIV in genital fluids is increased by STD- related inflammatory responses and exudates from lesions, making men and women who are STD-infected and HIV-positive more infective.[9-11] Furthermore, it has been found that when women have gonorrhea or chlamydial infection there is a disproportionate increase in CD4 lymphocytes, the HIV target cell, in the endocervix.[12] Studies have shown that treating STDs reduces the percentage of men in whom HIV is detected and the amount of HIV in ejaculate.[10, 13] In a recent community-based, randomized trial in the Mwanza district of rural Tanzania, treating STD-symptomatic individuals using the syndromic approach reduced HIV incidence in the study population by 42 percent.[14]

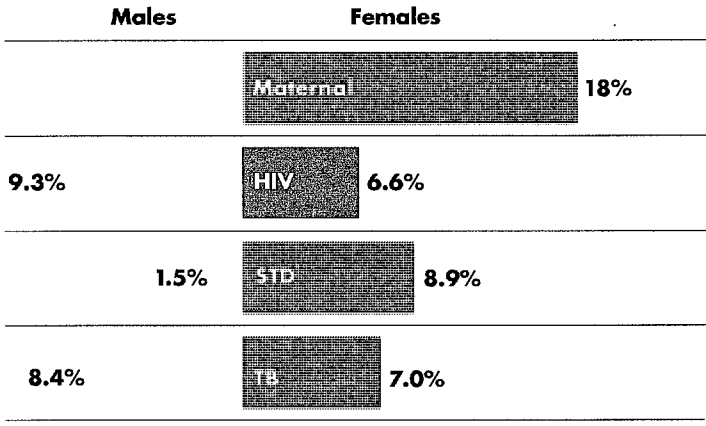
THE STD EPIDEMIC

THE MAGNITUDE

For several decades, STDs have ranked among the top five categories for which adults in developing countries seek health-care services.[15] Although in Northern and Western Europe there has been a spectacular decline in the incidence of STDs, particularly gonorrhea and syphilis, the situation in North America is more variable with increases continuing in inner-city minority populations.[16] In developing countries both the prevalence and incidence of STDs are still very high, with STDs making up the second cause of healthy life lost in women of 15 to 45 years of age after maternal morbidity and mortality.[17] In men, if HIV and other STDs are combined, sexually transmitted infections account for nearly 15 percent of all healthy life lost in this age group.[18]

Figure 1

COMMUNICABLE AND MATERNAL DISEASE BURDEN IN THE DEVELOPING WORLD



STDs can be categorized as curable and incurable. The common curable STDs are gonorrhea, chlamydial infection, syphilis, trichomoniasis, chancroid, lymphogranuloma venereum and donovanosis. The STDs that are preventable but not curable are the viral STDs and include human immunodeficiency virus, human papilloma virus, hepatitis B virus, and herpes simplex virus. Of the World Health Organization-estimated 333 million new cases of curable STDs in adults annually, there are 12 million new cases of syphilis, 62 million new cases of gonorrhea, 89 million new cases of chlamydial infection and 170 million new cases of trichomoniasis.[1] Table 1 shows the yearly incidence of curable STDs in 15-to-49-year-olds worldwide, with sub-Saharan Africa carrying the largest burden:[1]

Table 1

Estimated yearly global incidence of curable STDs in 15 to 49 year olds

North America	2-3%
Latin America and the Caribbean	7-14%
Western Europe	1-2%
Eastern Europe and Central Asia	3-8%
East Asia and the Pacific	1-2%
South and Southeast Asia	9-17%
Australia	1-4%
North Africa and the Middle East	4-7%
Sub-Saharan Africa	11-35%

In addition to curable STDs, it is estimated that as of mid-1995, about 18.5 million adults, and more than 1.5 million children, cumulatively, have been infected with HIV worldwide. It is projected that cumulative worldwide totals of HIV infections will reach 30 to 40 million by the year 2000.[18] Table 2 illustrates by continent the estimated distribution of HIV-infected adults (including AIDS cases) alive as of mid-1995.

Table 2

Estimated Number of HIV-Infected Individuals by Region

Region	Estimated Number of HIV-Infected Individuals Alive
Australia	20,000
East Asia and the Pacific	50,000+
Eastern Europe and Central Asia	50,000+
Latin America and the Caribbean	1.5 million+
North Africa and the Middle East	100,000+
North America	750,000+
Sub-Saharan Africa	8.5 million
South and South East Asia	3 million
Western Europe	450,000
Approximate total	14,420,000

Determinants of STD Epidemiology

An understanding of the determinants of STD epidemiology is important in designing a multifaceted approach to STD control that acknowledges the limitations of any single intervention.[19] These determinants can be categorized as the physiological micro environment, the behavioral/personal environment and the sociocultural macro environment.[20] Examples of each of these three broad categories are listed in Table 3.

Data from the U.S. and Europe indicate that adolescents and young adults are at higher risk of acquiring STDs for reasons related to influences from each of the three environments described above.[21] Data from the developing world is more limited but it is estimated that one in twenty adolescents contracts an STD each year.[22] Adolescents may be more likely to have multiple sexual partners, either sequential or concurrent partners, rather than long-term sexual relationships.

Earlier sexual debut increases the likelihood of exposure to an STD because of the longer period of sexual activity. Also, for social or economic reasons, adolescents may have difficulty using barrier methods (condoms or spermicides) that would offer protection from STD infection. Adolescents also may be more likely to have higher-risk partners. Biologically, young women appear to have an increased susceptibility due to hormonal changes and lack of immunity to certain STD pathogens.[23] Adolescents also may have less access to STD care because of lack of awareness, lack of money or the restrictive policies of clinics.[23]

In developing countries about one half of the population is under the age of 15. Consequently a large proportion of the population is entering the period of sexual activity and the age group with the highest STD prevalence. This results in a higher absolute incidence of STD cases in the developing world and also the potential for a worsening situation.[3]

Table 3

ENVIRONMENTS AFFECTING STD PATTERNS.*

Physiological micro environment

- Microbiologic
  - Vaginal pH (acidity)
  - Other STDs
- Hormonal
  - Cervical ectopy
  - Cervical mucus
  - Menses
- Immunologic
  - STD-specific immunity
  - HIV infection
  - Pregnancy

Behavioral/Personal environment

- Sexual behaviors
  - Age of first sexual intercourse
  - Number of sexual partners
  - Partner choice
  - Sexual practices
- Substance-use behaviors
  - Alcohol use
  - Drug use
- Health behaviors
  - Contraceptive use
  - Barrier method use
  - Treatment-seeking behavior
  - Compliance with medication
  - Self-treatment
  - Partner-treatment

Sociocultural macro environment

- Socioeconomic
  - Income levels
  - Gender inequities
  - Commercial sex
- Sociobehavioral
  - Community sexual norms
  - Community health beliefs and behavior norms
  - STD stigma
- Sociodemographic
  - Young age structure
  - Sex ratio imbalance
  - Urbanization
  - Migrant labor
- Political
  - Public health infrastructure
  - Social upheaval/conflict
  - Restrictive policies
- Technological
  - STD diagnostics
  - STD therapies
  - Prevention technologies (microbicides and female condom)
- Epidemiologic
  - STD prevalence
  - Sexual networking

**Adapted from reference 20*

Migration and rapid urbanization are demographic factors that play a major role in sexual behavior within a community and, in large cities, may result in a population consisting of many more men than women. As a result, casual and commercial sex are major modes of sexual expression, increasing the risk of infection. Poverty and gender inequality also foster the need for some women to turn to commercial sex as a means of survival. Their economic success is enhanced by the large number of men away from home who become their customers. These factors along with war, the absence of diagnostic and treatment services for STDs and the impact of HIV on STD epidemiology all combine to exacerbate the STD problem in developing countries.[24] Factors such as age and sex present a combined biological and behavioral effect on the epidemic. Economic instability and the deterioration of health and social services are contributing factors also.

There are differences in the proportion of the population practicing high-risk behaviors. For example, variations in the percentage of people who reported commercial and noncommercial casual sex over a 12-month period in Africa varied from 10 to 45 percent for men and from 3 to 30 percent for women.[25, 26]

The health-care-seeking behavior of community members greatly influences the health system's ability to deliver interventions aimed at STD control. Delay in seeking treatment for STDs has a significant impact on their spread since the longer a person is infected, the more opportunities there are for transmitting the infection to others.

THE HEALTH, SOCIAL AND ECONOMIC CONSEQUENCES OF STDS

STDs have effects that extend far beyond the individual's physical or psychological discomfort. The greatest impact of STDs is on women and children.[26] In women between 15 and 44 years of age, the morbidity and mortality due to STDs, not including HIV, are second only to maternal causes.[3] The prevalence of curable STDs in women is highly variable by region and risk behavior. Tables 4 and 5 below illustrate this variability.

Table 4

PREVALENCE OF STDs IN ANTENATAL CLINIC AND FAMILY PLANNING CLINIC ATTENDERS

	Gonorrhea	Chlamydial Infection	Trichomoniasis	Syphilis
Malawi[27]	4.7%	3.0%	31.8%	11.2%
Senegal[28]	1.6%	6.7%	16.7%	5.6%
Zaire[28]	1.6%	5.5%	18.4%	0.8%
Haiti[29]	4.0%	10.1%	34.7%	11.0%

Table 5

PREVALENCE OF SELECTED STDs IN SEX WORKERS

	Gonorrhea	Chlamydial Infection	Trichomoniasis	Syphilis
Philippines[30]	16.3%	12%	18.6%	4.6%
Cote d'Ivoire[31]	29%	5%	25%	25%
Mali[32]	11.3%	5.4%	4%	3.2%

Of note is that the majority of curable STDs in women cause subclinical or asymptomatic infection. For example, gonorrhea usually causes symptoms in men, allowing them to seek treatment, whereas women are frequently either asymptomatic or have minor symptoms. There are limited diagnostics available in developing countries for routine screening of asymptomatic women or even for testing of symptomatic women.[33]

Health consequences

PID and Infertility

In many parts of the developing world, pelvic inflammatory disease (PID) is the most common reason for admission to gynecological wards.[34] PID sequelae include infertility, ectopic pregnancy with subsequent maternal mortality, chronic pelvic pain, an increased risk of subsequent pelvic infections and a higher risk of hysterectomy.[34] Infertility as a result of PID accounts for 50 to 80 percent of the infertility in Africa; in Latin America, about 35 percent.[35] In cultures in which childbearing holds very high value, infertility as a consequence of gonococcal or chlamydial infection is tragic.[35]

Urethral Strictures

In developing countries, one out of seven males with gonorrhea has recently been reported to develop urethral stricture. Urethral stricture is a progressive condition that sooner or later calls for urological correction.

Adverse Pregnancy and Neonatal Outcomes

Treponema pallidum, the cause of syphilis, can cross the placental barrier and infect the fetus. *Neisseria gonorrhoeae* and *Chlamydia trachomatis* also cause morbidity in the mother and neonate.[36] For details of the impact of STDs on women and children, see Chapter 9.

Cervical Cancer

Cervical cancer, a global problem, is attributable in many cases to human papilloma virus, types 16 and 18, in particular. In most developing countries, screening programs for early detection of cervical cancer are not implemented due to the lack of available laboratory cytology. As a result, many women present at an advanced stage of the disease leading to high rates of morbidity and mortality.[36]

Social consequences

In addition to the health complications of STDs, it is also important to look at the painful social consequences of untreated STDs suffered primarily by women in the developing world. For many, social stigma and personal damage due to infertility and pregnancy wastage result in divorce or commercial sex work. And in Tanzania, a husband can return an infertile woman to her parents. In addition, the husband may request the return of her bride price.[37]

The complex interaction of infertility and other social factors in African society is depicted as follows:

> Marital instability caused by infertility and the spread of venereal disease caused by marital instability and sexual mobility can form a vicious cycle. The movement of abandoned or rejected barren women to urban prostitution has been noted in Niger, Uganda, and the Central African Republic. Similarly, in many of these societies, marital and sexual mobility on the part of the women is interpreted as a desperate attempt to become pregnant, and tolerance on the part of society as a means to maximize their chances of doing so...Once venereal disease was introduced into a community with some degree of sexual or marital mobility, its diffusion might have been assured by the existing customs. [Subsequently] the mobility itself [may have been] intensified to overcome the fertility effects.[38]

In addition to the impact of infertility, significant conflicts arise between couples, their families who become aware, and friends who are part of their support system. There is also the psychological and emotional burden of trust that is undermined, and the subsequent energy expended by partners to resume harmonious relationships. The number of incidents of violence and abusive behavior or retribution as a result of discovering an STD probably remains undocumented. What can be understood from experience is that an STD brings emotional consequences for those involved, including depression and its medical and social effects.

Economic consequences

Studies documenting the economic consequences of STDs are limited. The costs of pelvic inflammatory disease in the U.S. have been estimated to reach 3.5 billion dollars.[39] It also has been estimated that 5 percent of the total discounted healthy life years lost in sub-Saharan Africa is due to STDs, excluding HIV. HIV alone accounts for 10 percent of healthy life years lost.[3] More studies have been conducted recently that address the economic consequences of HIV.

Direct costs

Information about the costs of diagnosing and treating STDs in the developing world is scarce. It is known that the cost of using the most sophisticated diagnostic techniques exceeds the per capita national health-care budgets in many low-income developing countries. In fact, the cost of treating a woman for syphilis, chlamydial infection, chancroid or gonorrhea may exceed the per capita national health-care budgets. When considering the costs of screening and treating in a high prevalence area with poor laboratory facilities, it becomes evident that alternative strategies for reaching the population must be devised such as inexpensive screening tools, syndrome management or presumptive therapy without laboratory screening.[40]

Indirect Costs

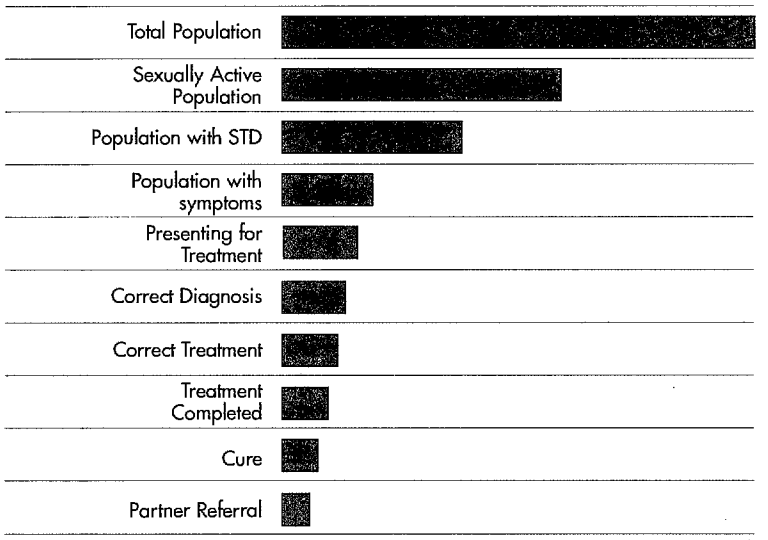
For women in an urban area of Africa, it has been estimated that chlamydial infection causes an average of 4.8 lost days of productive life, and for syphilis, 8.2 days per capita per year.[3] The costs in infant morbidity, debility and mortality add to the economic burden placed on a society as a result of STDs. For example, it is estimated that in a country where the prevalence of syphilis in pregnant women is 10 percent, some 5 to 8 percent of all pregnancies that extend beyond 12 weeks have an adverse outcome from syphilis.[41]

A World Bank report notes that the sum of the days of productivity lost due to HIV, syphilis and chlamydial infection almost equals the number of days lost due to malaria and measles.[3] Making treatment for curable STDs available represents one of the most cost-effective ways to improve health in the world.[3]

THE CHALLENGES OF STD CONTROL

Traditionally, STD control efforts have focused on diagnosis and treatment in the clinic setting. However, to have the greatest community impact, it is necessary to implement prevention activities and to find and treat cases as soon as possible.[24] This approach is supported by a model of health services in STD case management. The model describes the situation in which the number of people in a community who have or are at risk for STDs is far greater than the number who are seen in clinics and cured (see Figure 2.) Consequently, curative services alone contribute a small fraction to STD control efforts and will not solve the problem.

Figure 2
Operational Model of the Role of Health Services in STD Case Management



It is incumbent upon STD programs to provide intervention at the top of this diagram through educational efforts to reduce risk, make more condoms available, do case finding through partners and provide screening of antenatal women for syphilis. The synergy of efforts in this direction—prevention and case finding—in concert with improved clinical case management (the traditional focus) promises to be a more effective approach to STD control. It demands more attention to sociobehavioral aspects of STDs and the STD policy environment as well as a more consumer or patient-oriented approach to health service delivery. Once a community is educated and motivated to seek treatment for STDs, there is more pressure on clinical services to meet its demands. And once clinical services are more efficacious and user-friendly, it is more likely that the community will use them.

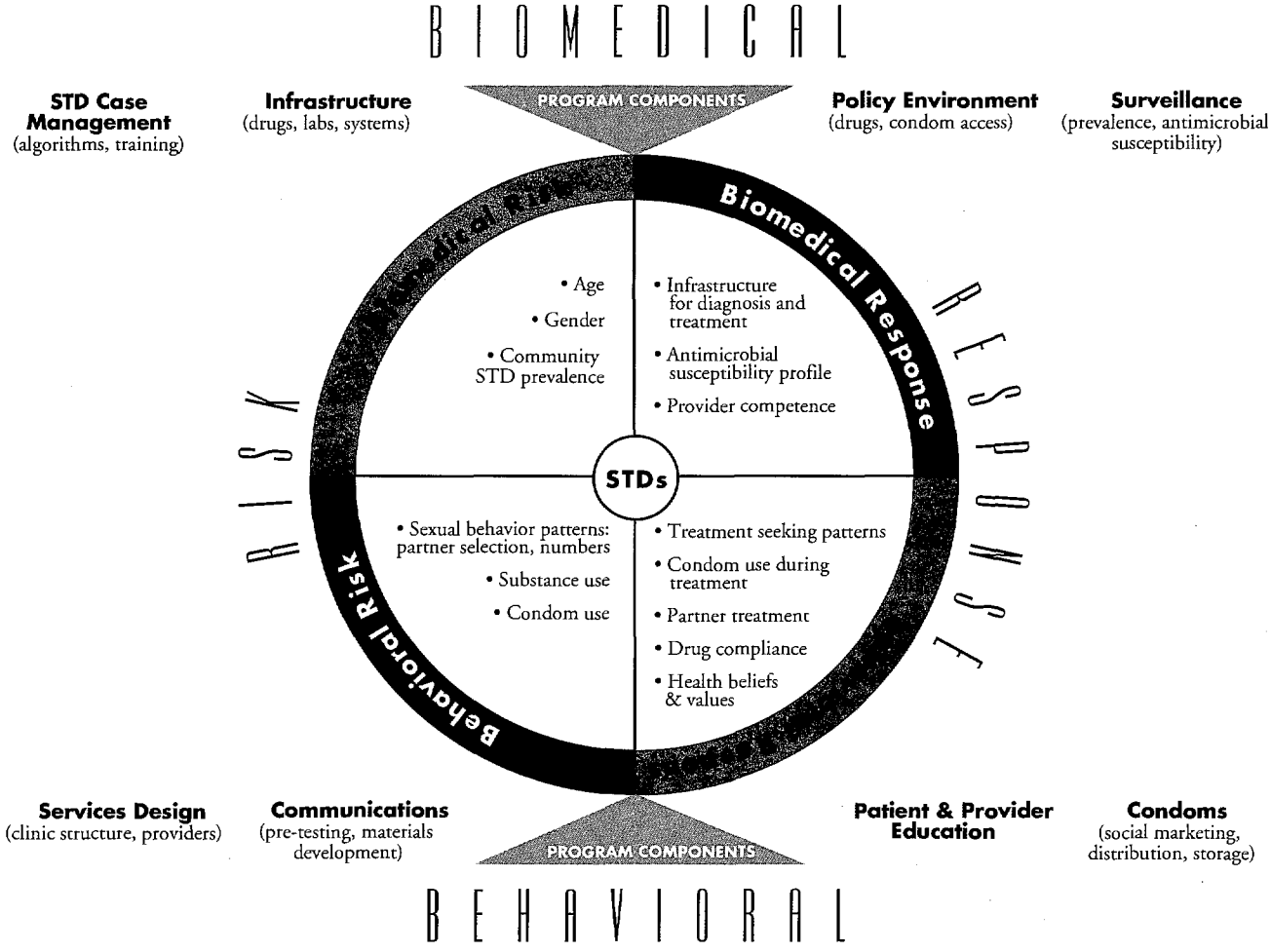
How accessible and acceptable services are to a community are important determinants of whether those who know they might be infected will actually seek care. Factors that detract from acceptability of services include high user fees, long waiting lines, lack of privacy, lack of empathy and acceptance by health providers and lack of effective drugs.[41-45] Indeed, in Cameroon in the early 1990s, nearly 50 percent of male patients with a history of acute urethritis in the previous 12 months decided not to seek care in the formal health sector.[45]

There is increasing evidence that a large proportion, and in some settings most, STD patients seek care elsewhere, such as from traditional healers, pharmacists, friends or in the marketplace. Data from Mwanza, Tanzania, and Nairobi, Kenya, show that offering accessible and affordable care, including effective drugs, can cause a shift of health-care-seeking behavior to official medical services.[24] In some settings, it may be preferable to opt for more innovative approaches, such as training pharmacists or traditional healers in the syndromic approach or by allowing the social marketing of STD treatment packages.[46] *(See Chapter 13.)*

In most developing countries, there is a significant disparity between what is needed for STD control and what is in place. Strategies for meeting these challenges are explored in greater detail in the other chapters in this book, and referenced here. Figure 3 summarizes the biomedical and behavioral factors affecting the risk of STDs, the response, and an STD program's critical elements.

Figure 3

BIOMEDICAL AND BEHAVIORAL FACTORS AFFECTING STD RISK, RESPONSE AND PROGRAMMATIC ELEMENTS



THE ROLE OF THE COMMUNITY AND THE CLINIC

STD control is not successful in most countries because of several factors, including the following: clinics are either unavailable or unacceptable; providers are not adequately trained or updated; and the correct drugs are unavailable, or when prescribed, taken incompletely or incorrectly. Effective STD management includes the following elements:

- Patients must know they are infected.
- Good services and drugs must be available.
- Patients must seek care promptly.
- The correct diagnosis has to be made and the appropriate treatment prescribed.

From the Patient's Point of View

Sione Latu has had a burning urethral discharge for two weeks. It did not go away completely after he took the pills that his friend gave him. He travels eight miles by a taxi that costs him three dollars (three times his daily wage) to go to the nearest clinic. He arrives at 10 AM and there are already 50 people in line. Many relatives, including his wife's cousin, are there and ask him what is wrong. He waits for two hours. The doctor asks him who he had sex with last week and he is embarrassed. The doctor sticks a swab up his penis, hurting Sione, and then asks him to wait for an injection and a prescription. A nurse then tells him he needs to come into a room with her for an injection. She tells him loudly in front of other patients that he needs a shot for his infection. He waits another hour until she has time to give him the shot. She asks him who his partner was and says that he must tell her to come in as well. She asks after his family to whom she is also related. She then hands him a prescription and says he should come back in two days for the test results to be sure that the drug is the right one. The prescription must be filled at the local pharmacy. The pill would cost him $17 that he does not have.

- Drugs must be used correctly.
- Instructions about sexual activity during treatment must be followed.
- Patients must refer their partners.

Prevention is a cost-effective approach that can greatly enhance current efforts and can be implemented through clinic-based and community-based interventions.

There are challenges external to the health-care system such as community norms, beliefs and attitudes; and other challenges inherent in the health-care system. Some of these can be influenced by an STD program manager. It is useful to consider what needs to be in place for prevention efforts in both the health-care system and in the community in terms of preventive and curative services.

In the community, the forces that have an impact on interventions initiated by the health-care system are vast. They include sexual beliefs, practices regarding STDs, attitudes toward the health-care system and economic resources. Prevention here refers to both preventing the initial infection and clinic services that manage the acute infection and prevent further infections. The distinctions are outlined in Table 6.

Clinic-based and community-based interventions for STD prevention and control are synergistic in their relationship. If community members are not educated about STDs, they are less likely to recognize abnormal symptoms and come in for care. On the other hand, if members of the community do not like or have trust in the clinic services, they are unlikely to come in even when they know they might be infected. Success in STD control is likely to result in a community when the messages and outreach are launched in a clinic that offers user-friendly, efficacious services. And an excellent clinic will have more impact on an educated community that is motivated to adopt risk-reducing behaviors.[47]

In any community, STD cases fall into one of four categories: asymptomatic (usually women) with no obvious symptoms; symptomatic in which symptoms are present but they are not recognized as abnormal by the patients; symptomatic and the patient recognizes the symptom as abnormal and seeks treatment; and symptomatic and the patient recognizes the symptom as abnormal but does not seek treatment.

Asymptomatic cases will only be treated if there are active efforts at case finding through partner contact and screening programs such as antenatal syphilis testing. The objective of case finding/screening is to identify individuals who are infected, but are not symptomatic, in order to treat them before they devel-

Table 6
Components of STD Control

PREVENTING INFECTIONS			
Health Care System/Clinic-Based Services	Risk reduction: group and individual advising and education at clinic site	Condom promotion and instruction. Linkages with condom distribution/social marketing (availability, affordability)	
Community- Based	Mass media, peer and community education	Condom distribution/ social marketing.Condom attitudes and practices (acceptability)	
TREATING AN INFECTION AND PREVENTING FUTURE ONES			
Health Care System/Clinic-Based Services	Patient education about treatment, transmission during infection, partner notification, behavior change to avoid STD in future.	Promotion of and education in the use of condoms.	STD case management; syndromic approach used when lab diagnosis not possible. Proper antibiotics prescribed appropriately. Drugs available in clinic. Partner contact system Case finding of asymptomatic patients Diagnostics available at referral labs.
Community-Based	Educational programs address local beliefs and practices about treatment	Distribution during partner outreach	Drug availability and community attitudes

op complications and sequelae. For symptomatic cases, one important approach that is not commonly encountered is to reach the community with messages that encourage men and women to seek care as soon as they experience symptoms. For women it is important that they understand the different types of discharge they experience and which types warrant seeking care. Early treatment can effectively reduce transmission and sequelae. Unfortunately, as shown in several studies, patients often wait as long as one month to seek care through clinic services.[48]

Behavior Change

There are several components in the prevention of STDs. Behavior change is key, and efforts are channeled toward risk reduction through mass media and interpersonal initiatives. One element of this prevention strategy is to encourage community members to reduce their risk of contracting an STD by using condoms, decreasing the rate of partner change as well as change in their selection of partners. Intense, sustained interventions have better results than shorter, less intense ones.[49]

One way to increase the intensity of interventions is to use a combination of mass media and interpersonal strategies. However, both approaches pose challenges.

The use of mass media requires financial resources and media access, which are often unavailable. Interpersonal initiatives such as one-on-one counseling pose a challenge because they are labor-and human-resource-intensive.

It is often difficult to provide risk reduction counseling at clinic sites because of a personnel shortage and infrastructure limitations. Depending on community attitudes about the status of the provider who delivers the health message, non-physicians and non-nurses can be used to do one-on-one or group risk reduction counseling in the clinic setting. Regardless of who does the counseling or advising, training will often be necessary if they are to perform this function effectively. Training *(see Chapter 6)* necessitates time away from clinic work, the availability of trainers and motivation on the part of the health workers to take on this role. These are all potential constraints to the accomplishment of this challenge.

Health-Seeking Behavior

Health-seeking behavior is both a function of attitude towards disease and sex and the accessibility and quality of health-care facilities that deal with STDs. Several characteristics of many clinics act as deterrents to their use. These include long travel distances and waiting lines, stigma and user fees. The introduction of user fees in 1989 in Kenya and in 1992 in Zimbabwe resulted in a dramatic decline in clinic use.[19]

Studies have found that a common complaint of adults attending clinics for STD care is the lack of privacy and confidentiality. Patients in many communities have reported that the purpose of their visit has not been kept confidential.[48] The judgmental and unsympathetic attitudes of providers have also been found to have a profound impact on patients' opinions of services. In Ethiopia, informants in a study of STDs in a community stated that "Providers should not scold." Community members often report a preference for traditional healers who are perceived as sympathetic and caring.[44]

Making STD services private and confidential, and providing them in a nonjudgmental, supportive manner are key in getting patients to come in when they have STD symptoms. It is incumbent on STD managers to ensure that clinics establish policies and design services so that patient matters are kept confidential and patients have the opportunity to be interviewed and examined in private. In addition, providers might need to participate in programs in which they can explore their attitudes toward STD patients and learn more effective ways to interact with them so that clients do not feel alienated in the clinic environment. If clients are comfortable, they are more likely to hear and accept instructions and return when necessary. (Behavior change in the clinic setting is discussed in detail in Chapter 10.)

The Promotion of Condoms and Other Barrier Methods

Condom promotion, a foundation for effective primary prevention efforts, is a challenge in many countries. Effective condom promotion requires the ready availability of good quality and affordable condoms that are properly stored. In addition, providers must be convinced that condoms are a good idea, local distribution efforts including social marketing must be effective and community attitudes must support condom use. The Ministry of Health also has to be willing and able to allocate funds to procure condoms, a situation that is not always in place. (Chapter 5 deals in greater detail with condoms and other barrier methods for STD prevention.)

STD Case Management

Prompt and effective treatment of STDs is an essential component of STD control. The goals of case management are to cure the disease, prevent complications and sequelae, prevent transmission of the treated disease to others and reduce HIV transmission. Ideally this includes early diagnosis and treatment to prevent further transmission and the development of complications. Several factors interfere with the ability of many countries to implement effective STD case manage-

ment. These include the large number of asymptomatic infections in women, inadequately trained health providers, the lack of appropriate diagnostics and the lack of effective drugs.

Syndrome Management

In the case of symptomatic STDs, the syndromic approach to management—treatment based on a constellation of clinical signs and symptoms—is advocated. This approach is pragmatic in that it does not require laboratory facilities, often unavailable in many countries, and patients are treated at the time of their visit so they are not lost to follow-up. This contributes to the prevention of sequelae and further transmission. In addition, all major pathogens are treated, averting the omission of treatment due to false negative laboratory results. (Syndrome management is addressed in greater detail in Chapter 8.)

Currently, in many countries STDs are managed using clinical diagnosis or etiologic diagnosis employing suboptimal or incomplete diagnostics. Both of these approaches tend to be unreliable because many co-infections are missed. Because they were trained in treatment based on etiologic diagnoses, many physicians are reluctant to use the syndromic approach. Local data collection often highlights the inadequacies of clinical diagnosis. Training providers in the overall rationale and utility of syndrome management and in the use of flowcharts is critical to its success. Indeed, the application of this approach requires provider behavior change that can be almost as difficult to achieve as the behavior change requested of community members.

Drugs

A major condition for successful STD management is the availability of effective drugs, which are lacking in many countries. There are several major problems and, unless resolved, they obviate the potential for successful STD prevention and control efforts. The problems include the following:

- Available drugs that are ineffective due to the development of antimicrobial resistance
- Effective drugs for STDs that are available only in the private sector, subject to additional taxes and thus unaffordable to a vast majority of patients with STDs
- Effective drugs that are not included on the national essential drug list
- Health-care providers continuing to prescribe drugs to which the organisms have developed resistance despite the availability of alternatives
- Pharmacists selling drugs over the counter in doses lower than those recommended when the customer can not afford to buy the full, recommended dose
- Out-of-date or inactive drugs
- Drug vendors selling drugs that are ineffective and/or inadequate

The development of antimicrobial resistance has made the treatment of gonorrhea and chancroid more complicated and more expensive. In most African countries, approximately half or more of all gonococcal isolates are producing penicillinase, making treatment with the inexpensive penicillin useless. In addition, resistance to another inexpensive antibiotic, tetracycline, has been spreading rapidly among gonococcal strains.[24] Gonococcal resistance to quinolones has been reported in the U.S. and Asia.[50]

It is important that there be a system of monitoring antimicrobial resistant strains of STDs as they develop, that the means of procuring more effective drugs be found and that providers be updated periodically about current recommendations. In addition, the ability of patients to pay for the most effective drugs must be considered and programs must be put into place that facilitate their ability to get the right drugs. Countries must include the most effective antibiotics for STDs on their essential drug lists, and ministries of health must confront the cost issues. It is urgent that there be a concerted effort to solve the widespread problem in most countries of the unavailability of effective drugs. One approach might be sharing the cost burden for the more expensive antibiotics between developing and developed countries.[3]

Even if all of the above elements were in place in a country, there would still be work to do to treat patients fully for any STD infection. The correct drug in the correct dose for the correct duration are all part of effective treatment. Currently, little effort goes into educating patients about their own drug treatment. Patients might be better able to help fight off the threat due to the increasing number of antimicrobial resistant strains if they understood the importance of taking full prescribed courses of antibiotics and had the means to purchase them.

Prescribing practices of providers also affect the success of treatment. Practices that result in ineffective therapy include polypharmacy, whereby several antibiotics with overlapping effects as well as unnecessary creams or ointments are prescribed, resulting in increased cost to the patient as well as unreasonable demands on the patient's ability to remember and comply with instructions. Inadequate or nonexistent patient education about the prescribed drug, including instructions about how, when and for how long to take it, result in poor patient compliance with the required treatment.

Another important hindrance to successful treatment is providing an incorrect prescription, whereby an antibiotic that is ineffective against the causative organism is prescribed. In addition, it is well-known that patients have great difficulty remembering to take several doses of a pill a day for several days, much less being able to afford them. Ideally, providers should try to prescribe the drug that requires the fewest doses for the shortest possible period of time and with the fewest side effects. With this sort of regimen, successful treatment of the infection is more likely. (Drug issues are more fully discussed in Chapter 7.)

Partner Management

The treatment of partners is a cornerstone of the STD case management approach. Because of the stigma associated with STDs and the accompanying social costs, and the lack of established systems, often partner notification is not executed fully. Depending on how it is implemented, partner notification can be labor-intensive, costly, and made more difficult because of the stigma attached to STDs. There are several options that are discussed in more detail in Chapter 11. Of note is that migrant labor and commercial sex trade, which lead to anonymous sexual encounters, also decrease the success of partner notification efforts.

Screening

Screening asymptomatic individuals, especially women, for STDs is limited by the unavailability of inexpensive, accurate and rapid diagnostics.[33] One major screening test, the nontreponemal syphilis test, is simple and widely available but it is not routinely used because of financial and logistical constraints.[51] (A more detailed discussion of STDs and pregnancy can be found in Chapter 9.)

Interventions Focused on Core Groups

In populations in which a small number of individuals form a high proportion of sexual partnerships, the greatest impact on STD control is achieved by interventions directed at this group, which is most likely to be infected and to infect others.[3,52] In many countries, these are people in urban areas whose sexual behavior may have changed because of crowded conditions, poverty, loneliness, and alienation. Commercial sex workers, adolescents and itinerant workers often fall into this category as well. The distinguishing feature of these groups is that they have a high rate of sexual partner change. Although labeling groups as "core" can produce stigma, the concept is intended to be epidemiological rather than moral or social.

The rationale for intensive interventions with these groups is clear. Focusing on these individuals should achieve the greatest impact on the spread of STDs, partly because there is interaction between core and non-core group members at some point. This has proven effective in Thailand, where condom-only brothels have resulted in significant reductions in STD rates.[53] But applying the concept of focusing on core groups is challenging because in some settings groups

such as commercial sex workers are not socially identifiable and, even if they were, there would be concern about stigmatizing them. Peer education has been one approach to avoiding stigmatization.[3] (More details on targeting interventions can be found in Chapter 13.)

Management

The management structure of the STD control program is critical. A good relationship between the STD control program and related programs such as HIV/AIDS control, family planning, maternal and child health and health education maximizes the impact of STD control and prevention efforts. The administrative structure of the STD unit is also important. Responsibilities and lines of communication should be clear. Ongoing training in technical and administrative skills should be a priority so that a professional team does not depend on one or two key personalities. A single STD activist with a strong personality who shoulders the entire program is not sufficient. The more the wisdom is shared, the more clinic managers in outlying areas are motivated and decision making is dynamic, the more likely program initiatives will be supported and sustained over time. (STD program management is discussed in Chapter 2.)

Training

Training and updating providers in appropriate STD case management are priorities for improving STD care. The syndromic approach to STD case management is more than a solution to a resource problem. It is an approach that respects the available time that patients have by treating them at their point of first encounter with an approach that does not require their return. Also it is likely to be effective because it treats the most prevalent infections in their area. In addition, provider training that addresses the sociobehavioral aspects of STD prevention will result in clinical approaches that are respectful to the patient. This facilitates the understanding of STD transmission, treatment and prevention. Providers should progress to providing care that integrates diagnosis and treatment with risk reduction advising, condom promotion, and partner contact. (Training is more fully addressed in Chapter 6.)

Laboratory Services

Depending on the size of the country, it is important that one or more laboratories be prepared to conduct the essential epidemiological and microbiological research necessary for surveillance efforts. Where possible, laboratory tests with a short turnaround time could be available to nearby clinics to assist in treatment decisions, particularly in cases that are unresponsive to the first course of treatment. The laboratory can play an essential role in epidemiological and microbiological surveys, antimicrobial susceptibility studies and in the validation of treatment and management approaches. (Chapter 12 discusses these issues in more detail.)

Surveillance, and Monitoring and Evaluation

The establishment of systems of monitoring and surveillance are key to sustaining effective prevention efforts. Monitoring antibiotic susceptibility and prevalence is the basis for updating the syndromic management flowcharts and for selecting the antibiotics that should be included on the country's essential drug list and recommended in the national STD treatment guidelines. Monitoring STD trends and cases makes it possible to project resource needs and program impact. Monitoring provider performance provides the information necessary for continued training. (Full details on surveillance can be found in Chapter 15, and on STD program monitoring and evaluation in Chapter 14.)

Research

Epidemiological research is needed to accomplish the following:

- Collect baseline data on STDs and their complications.
- Develop methods for disease surveillance.

- Learn more about the natural history and risk factors for STDs.
- Learn more about the impact of HIV infection on the natural history and response to treatment of other diseases.
- Establish the dynamics of core groups.
- Delineate the factors determining diverse epidemiological patterns.

Intervention trials and feasibility studies, demonstration projects and community-wide interventions, both behavioral and medical in nature, are needed. Examples include the impact and sustainability of risk reduction campaigns on youth, syphilis screening for pregnant women and the use of syndromic management. Operations research should address the actual cost of service delivery and the impact of syndromic management on the cost of integrating STDs into other services.[3] Operations research can be very useful in assessing the feasibility of STD treatment and control in family planning and other settings. Operations research has also been instrumental in implementing decentralized services for syphilis screening and changes in laboratory screening approaches.

Behavioral research is needed in designing and evaluating both services and messages. A targeted intervention research approach has been used in several countries to assess local beliefs, practices and attitudes relating to STD health-care services. The research forms the basis for the design of services and the develop-

Table 7

Policy Environments that Affect STD Control

Resources for STD Prevention and Treatment

- Budget allocations for STD treatment relative to other diseases
- Private sector commitment to STD care
- Provision of the recommended antibiotics to public sector clinics and inclusion of effective antibiotics on essential drug lists

Restrictive Policies and Procedures

Women

- Policies that restrict access to services and require a husband's permission for exams, drugs and barrier methods

Youth

- Policies that restrict access to clinical services for STDs and family planning
- Policies that restrict access to condoms

Condoms and STD drugs

- Tariffs that make importation costly and cumbersome
- Restrictions on distribution of condoms to minors or unmarried women

Services

- Restrictive laws that prohibit diagnosis and treatment of STDs by nurses, decreasing access to services
- Policies that encourage clinic-based, laboratory-dependent and physician-managed STD services exclusively

ment of educational and motivational messages. Better data are also needed on sexual behavior and its relationship to STD incidence and prevalence. This data can be used to improve knowledge about transmission dynamics and plotting spread, and in devising control programs.[52] *(See Chapter 13.)*

Studies that look at the impact of STDs and other diseases are needed to make policy choices about how to allocate resources among different disease programs. In addition, the impact of STDs on other family members is important information as is the economic impact on households.

THE POLICY ENVIRONMENT

In most countries, there are policies in several major areas affecting STD prevention and control efforts which, if changed, could enhance these efforts. As seen in Table 7, aspects of the policy environment that warrant review fall into the major areas of (a) resources for STD prevention and treatment; (b) restrictive provisions of health delivery systems, and (c) service access issues. STD managers would be wise to review these aspects of the policy environment in their countries. If the policies are restrictive or if they inhibit STD prevention and control efforts, managers can advocate for policy changes.

It is understood that factors such as poverty, gender inequities and social unrest that contribute to STD prevalence are beyond the direct influence of the STD program manager. However, a manager's influence is not limited to clinic services. STD program managers should seize opportunities to ensure condom availability, community mobilization and education, and advocate for policies that have an impact on STDs in the community.

CONCLUSION

The global burden of STDs and their effects is sobering. Although there are resource issues that are beyond the direct influence of providers and managers, it is possible to improve services in the areas that are within their sphere of influence. Program managers are in a position to advocate for interventions and resources that will result in STD prevention and prompt and effective treatment. Achieving improvements is within the reach of program managers who are committed to this endeavor.

The handbook is designed to assist program managers in this critically important task. It addresses the biomedical, social, behavioral, educational and management aspects of STD prevention and control. Managers are encouraged to use the handbook as a resource and to seek other opportunities for their staff to improve their practices as well. It is only through a supportive infrastructure and excellent clinical practice that there can be progress in the area of STD prevention and treatment.

Managers must meet the challenges posed by STDs by coordinating private and public practices, strengthening supportive infrastructures and community linkages, incorporating sound management practices, establishing links with other ministries, and providing active and informed support for excellence in the clinical practice of health workers at all levels. Through concerted, comprehensive efforts, strides will be made in preventing STDs and mitigating their effects.

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CHAPTER 2

Guidelines for the Management of STD Control Programs

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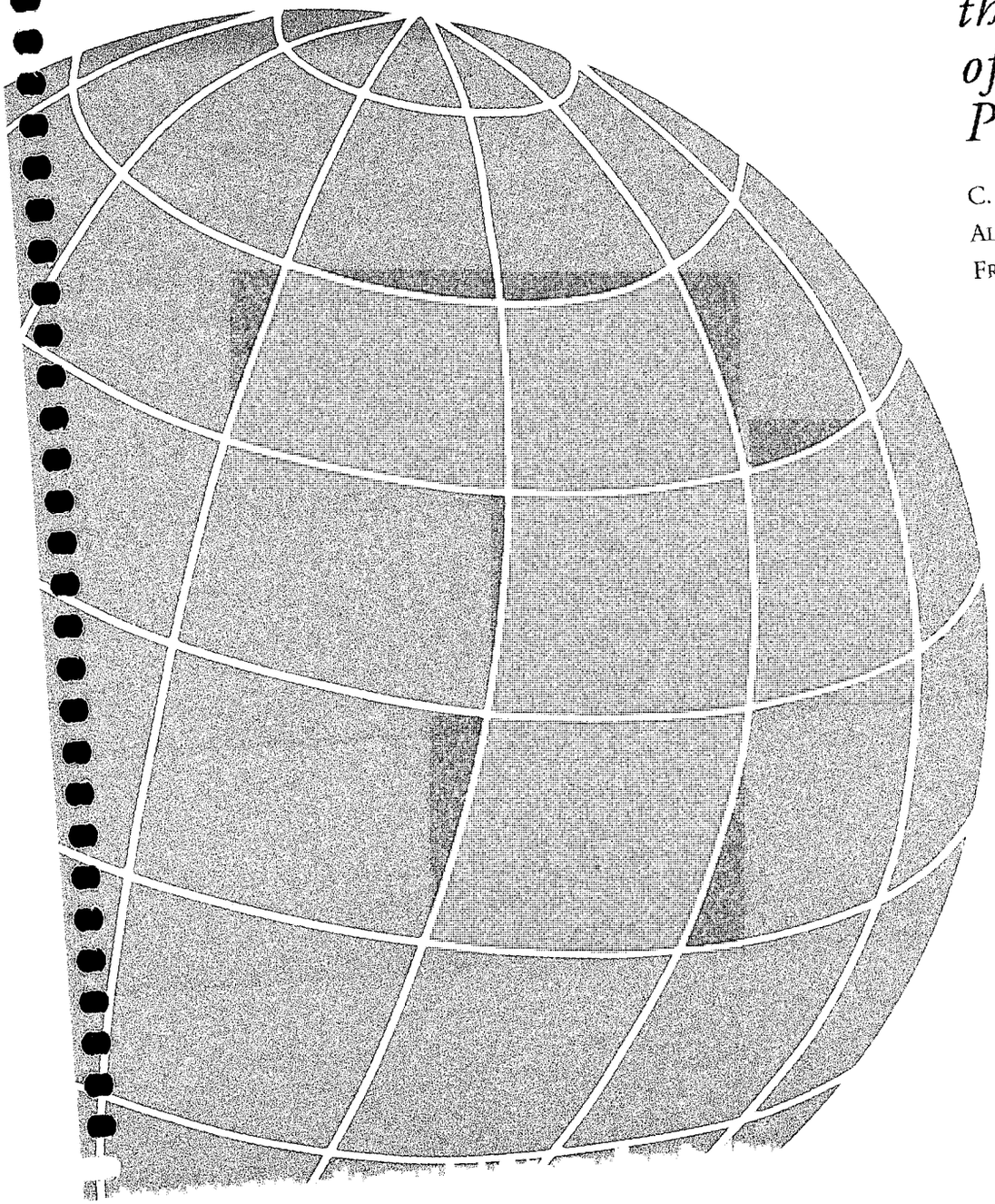


preview CHAPTER 2

Guidelines for the Management of STD Programs

INTRODUCTION

This chapter describes the role and structure of STD program management and the process for planning and implementing STD control activities.

PROGRAM MANAGEMENT AND STRUCTURE

Program management is the organization and control of available human, material and financial resources to ensure that they are being used effectively and appropriately.

PROGRAM DELIVERY AND COORDINATION

Coordinating resources and activities within a program and with people from other groups (both private and public sectors) is an important management task that should take place at every phase of the program.

VERTICAL VERSUS HORIZONTAL PROGRAMS

STD program activities can be delivered through vertical or horizontal systems. In a vertical system, services are provided through special STD clinics; in a horizontal system, such services are provided at general health-care facilities. There are advantages and disadvantages to both.

PROGRAM PLANNING AND IMPLEMENTATION

STEPS

- A **situational assessment** is conducted to obtain a clear picture of a country's STD challenges, available resources and the political, legal and social factors that might influence the program.
- A **political commitment** makes it possible to obtain resources, promote safer sexual behavior, introduce sex education into the school curriculum and promote condom use.
- A **national STD policy** indicates a government's commitment to addressing the STD problem and provides clear policy guidelines.

- A **selection of program priorities** has to be made because STDs and resulting complications are not distributed evenly throughout a population and, in many situations, resources are scarce. Much of this depends on identifying "core groups."
- **Setting objectives and designing strategies** is essential for effective program management. Objectives state in broad terms what the program is expected to achieve. A strategy describes how specific objectives will be met.
- **Planning the implementation** of control activities involves coordination with all the key components, such as, the Essential Drugs Program (EDP), which ensures that appropriate drugs are made available to first-level health-care facilities.
- **Support components** essential to developing and implementing an STD control program that should be included in the work plan include the following: guidelines; training; logistics (including drugs and condoms); laboratory services; research; and surveillance.
- **Resource mobilization** requires frequent advocacy and negotiations with many sectors, including national governments and international partners.
- **Monitoring** is the process of assessing how well various program activities have been implemented. It should be both quantitative and qualitative.
- **Evaluation** is a periodic assessment of whether a program is meeting its planned objectives. Evaluation results are essential to revising less successful program components, planning program expansion, or developing or implementing new strategies.

CONCLUSION

Understanding the essential aspects of program management and the planning process will allow program managers to develop cost-effective STD control programs that can accommodate social, cultural, epidemiological and political variations and make the best use of existing resources.

INTRODUCTION

STD control programs must be designed to address each country's unique epidemiological situation, behavioral patterns and cultures. Consequently, no standard STD program will be appropriate for every country, and even within a single country, a control program is likely to change over time to address changes in STD epidemiology, in society and in control opportunities.[1]

Despite these variations, programs inevitably share many similarities. The objectives of all STD programs are similar, and the requirements for an adequate management structure are the same, even if such programs differ in operational detail. This chapter describes the role and structure of STD program management and the process for planning and implementing STD control activities.

The objectives of STD control are the following:

- Interrupt the transmission of sexually acquired infections.
- Prevent the development of diseases, complications and sequelae.
- Reduce the risk of HIV infection.

An STD control program seeks to achieve these objectives through a management structure that delivers both education to prevent infections and clinical services to treat infections. Preventing infections involves promoting sexual and reproductive health, safer sexual behavior including condom use, and assuring that good quality, affordable condoms are available. Treatment involves promoting health-care-seeking behavior, particularly among those at increased risk of acquiring STD, and providing accessible, acceptable and effective diagnosis and treatment for symptomatic and asymptomatic STD patients and their partners.

Successful management of these activities requires an STD management unit in the Ministry of Health. This unit should be responsible for the following:

- Designing strategies, setting priorities, and planning and supervising control activities
- Coordinating resources and activities within the program and with other programs or sectors of the health-care system, both public and private
- Monitoring, evaluating and revising the control program or planning its expansion

To fulfill its responsibilities, the STD unit should interact with the Ministry of Health and with health workers at various levels of the health-care system, both in the public and private sectors. The unit should collaborate with other programs, medical associations and organizations and should involve different sectors of society, including nongovernmental organizations (NGOs) and the business sector. It is particularly important to collaborate with primary health care and maternal child health/family planning (MCH/FP) programs and to establish close links or integration with HIV/AIDS programs. Such collaboration requires a well-defined management structure.

PROGRAM MANAGEMENT AND STRUCTURE

Program management is the organization and control of available human, material and financial resources to ensure that they are being used in the most effective and appropriate manner to achieve a program's objectives.

STD UNIT

An STD program should be managed by an STD unit in the Ministry of Health. This can be an independent unit, part of the national AIDS control program or part of a larger division such as the communicable diseases program. Because of the close linkages between HIV/AIDS and the traditional STDs, it is recommended that STD and AIDS programs be integrated. However, in such an integrated STD/AIDS program a manager should be responsible for STD control. If the STD and HIV/AIDS programs are not integrated, close collaboration and coordination between them are essential.

The STD unit should be headed by a full-time program manager with a public health background. This person should report to the HIV/AIDS program manager or to someone higher in the Ministry of Health who can make policy decisions and issue guidelines. The program manager represents and promotes the STD control program not only within the Ministry of Health, but also with opinion leaders, NGOs, the private sector, and donors.

In larger countries where disease control activities are decentralized to states, districts or municipalities, it is best to appoint STD program managers at each of these levels. Even if it is not possible to appoint full-time STD managers for state, district or municipal programs, staff responsible for disease control at these levels must be sensitized to the importance of STD control and involved in planning the control program. Whether full- or part-time, these regional, district or municipal STD managers should report through the appropriate channels to the national STD program manager.

In most countries, however, management and implementation of STD program activities will be integrated into the existing health-care system with no separate management structure, except for the central STD unit.

TECHNICAL STD COMMITTEE

A national technical committee should be formed to assist the STD unit in technical areas of STD control. In smaller countries there might be one technical committee for both HIV/AIDS and STD. The committee should assist in drafting a national STD policy and in developing strategies and approaches. It can also advise the STD unit on technical issues, including standardized treatment guidelines, national adaptation of patient management flowcharts, identification of research issues, review of research proposals and STD surveillance.

The national STD committee should be composed of key experts from different fields: STD specialists, microbiologists, public or community health specialists, and information, education and communication (IEC) experts. Others such as pharmacists and gynecologists can be consulted when required.

Because most STD programs will collaborate with the private and NGO sectors, it is advisable to include representatives from these sectors on the committee. A broad-based committee eases the process of obtaining peer approval for and national consensus on strategies and approaches. A broad base of support is particularly important in countries where the STD program is developing a more public-health approach, often against initial resistance from established and influential clinicians. A broad-based STD committee also strengthens the ability of the program manager to obtain a political commitment to STD control and negotiate adoption of a national STD policy.

PROGRAM DELIVERY AND COORDINATION

The STD unit should prepare a plan for STD control, ensure the implementation of planned activities, monitor and evaluate the program, and use monitoring and evaluation results to revise plans or to expand the program.

Coordinating resources and activities within a program and with people from other programs or sectors of the health-care system is an important management task that should take place at every phase of the program. An important principle of coordination is that early involvement in planning leads to greater cooperation and collaboration. For example, providing STD clinical services for women through MCH/FP and antenatal clinics (ANC) can best be planned in close consultation with those programs. Similarly, a program to control congenital syphilis should be developed with the national MCH/FP program.

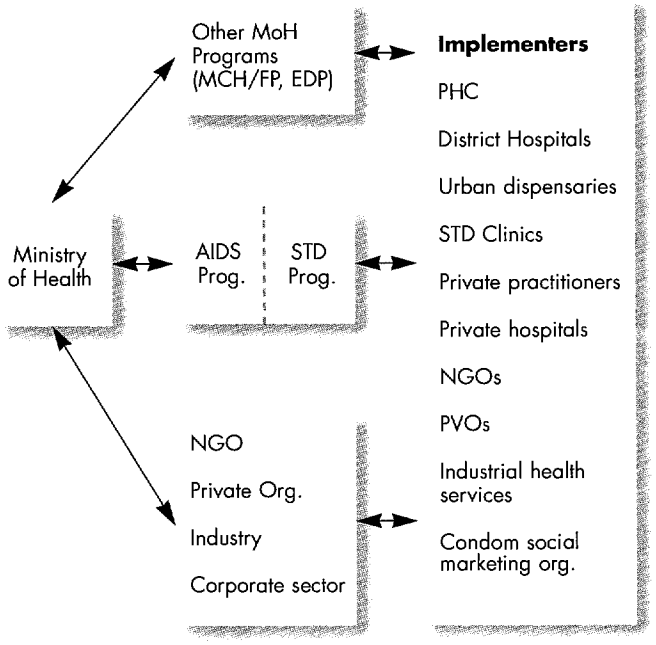
Coordination can be achieved through regular meetings with interested programs. To ensure that proper and consistent STD prevention messages are integrated into the HIV/AIDS control program, regular meetings should be held with IEC staff.

Communication between the STD unit and the Ministry of Health is usually straightforward, with an established line of reporting. Channels of communication with other programs in the Ministry of Health and with other ministries need to be established and made as simple and direct as possible.

COORDINATION WITH PUBLIC SECTOR IMPLEMENTERS

It is particularly important to communicate with and involve the actual implementers of the program—the staff at different levels of the health-care system. Depending on the program strategies that are adopted, implementers may include public sector STD specialists, public sector medical officers, paramedical staff, private sector health-care providers, NGO staff and health-care workers in industries.

Figure 1
PARTNERS IN PROGRAM IMPLEMENTATION



Health-care workers at the peripheral levels of the system are usually overworked and often reluctant to take on new tasks and responsibilities. These constraints can best be overcome by involving the first-line workers in the planning process, particularly in implementation planning.[2] Once implementation begins, there should be frequent supervision and communication between implementers and program managers to ensure timely feedback on problems or constraints.

Annual program review, evaluation and planning meetings may be organized. Getting regional or district managers to participate in such meetings will serve at least three important goals, which are the following:

- Provide communication opportunities about program implementation with the central STD unit (vertical communication).

- Provide opportunities for managers and implementers to share experiences (horizontal communication).
- Foster a sense of ownership of and commitment to the program.

To facilitate the involvement of regional, district, municipal and peripheral staff, job descriptions and terms of reference should be clearly defined. In addition, lines of communication for the flow of information from the center to the periphery, as well as from the periphery to the center, should be spelled out. Feedback from the central level to the peripheral levels is crucial to ensure continued commitment of the health-care workers to the program.

Coordination with the Private Sector

Initially, private sector health-care providers might not see any benefits in collaborating with a national STD program. But by involving them in the planning process, the STD program manager can hear their views and, accordingly, develop approaches that are mutually beneficial. For example, getting private practitioners to adopt standard treatment regimens of proven efficacy contributes to more effective STD patient management. This, in turn, enhances the status of the private practitioner, which might increase his patient load. Finally, it contributes to achieving one of the desired outcomes of the program. Figure 1 shows the lines of communication among different partners in STD program development and implementation.

Vertical versus Horizontal Programs

STD program activities can be delivered through vertical or horizontal systems. In a vertical system, clinical services for management of STD patients are provided through special (dedicated or categorical) STD clinics; in a horizontal system, such services are provided at general health-care facilities. In an integrated, horizontal program, most patients are managed at the first level of the health-care system; in a vertical system, patients are usually referred to specialist STD clinics.

Box 1

A Combination of Vertical and Horizontal Components Ensures Program Delivery

STD programs are best delivered through a combination of vertical and horizontal program components.

- A vertically organized central STD unit is responsible for planning, coordination, preparation of guidelines, development of new strategies and approaches, quality control and supervision.
- Program implementation at the district and peripheral levels is integrated into the existing health-care system.

Both approaches have advantages and disadvantages. The advantages of a vertical system with categorical STD or dermato-STD clinics are that these clinics are usually well-equipped and well-staffed, often with an STD specialist. Laboratory services are often available, and the clinics offer quality patient management. The disadvantages are that most of these clinics are located in major urban areas, making them inaccessible to the majority of the population; special STD clinics in most countries are perceived as stigmatizing; and they are relatively costly. Utilization rates by women may be low.

A horizontal system of service provision, with STD care integrated into primary health care, is more accessible and less stigmatizing, increasing acceptability, particularly by women. The quality of patient management, however, varies greatly. Often staff members are poorly trained and overworked, and specific STD drugs and even rudimentary laboratory services are not available. In the public sector, staff attitudes toward STD patients may be negative.

Vertical and Horizontal Components in One Program

In many countries components of both a vertical and a horizontal system coexist. Usually the program is best managed by a vertically organized STD unit at the central level, with program implementation integrated into existing structures at the district and peripheral levels. This is the ideal situation, assuming that the primary health-care system functions.

Categorical STD clinics already exist in many countries, especially in the larger cities. In this situation, rather than dismantling the clinics they could be transformed into referral and training centers as a component of upgrading STD case management in primary health-care clinics. It is often best to pilot-test new approaches and strategies using a vertical approach. But wider implementation requires integration of control activities into the existing health-care system.

Interventions with and service delivery for specific target groups might require a vertical approach to management and implementation. In the long run, however, integration usually offers better prospects for both acceptability and sustainability.

Program Planning and Implementation

Planning is the process of outlining how to implement, monitor and evaluate a program. Monitoring and evaluating, in turn, influence further planning, creating an ongoing cycle of response *(see Chapter 14)*.

Steps in STD Program Planning and Implementation

Planning and implementing STD control activities involve the following steps or phases:

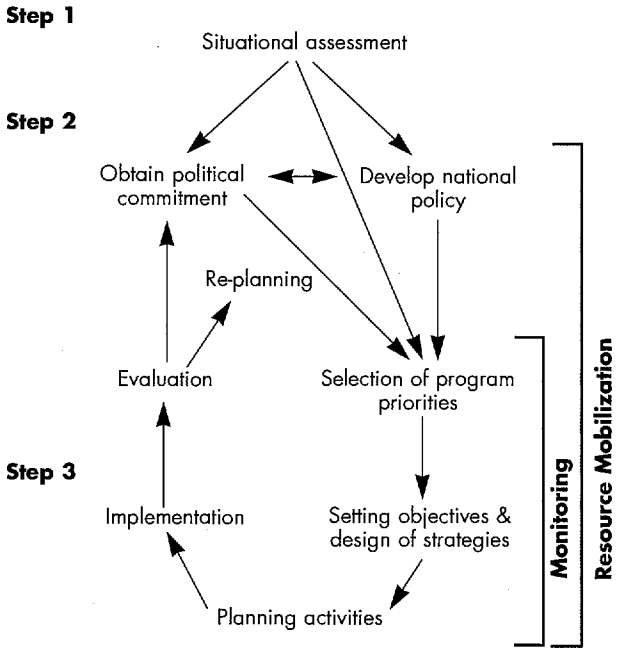
- Conduct a situational assessment.
- Obtain political commitment.
- Develop a national STD policy.
- Select program priorities.
- Set specific objectives and design strategies.
- Plan implementation.
- Plan support components.
- Mobilize resources.
- Monitor and evaluate.
- Revise a plan or plan to expand the program.

It may not always be possible or even desirable to adhere to the sequence of steps outlined above. For example, in many countries a situational assessment will indicate a lack of epidemiological data on STD prevalence or incidence or on the antibiotic susceptibility of a common STD. Yet planning of STD control measures should not be delayed until comprehensive studies have been completed. Instead, these measures should be based initially on expert opinion and, possibly, on experiences in neighboring countries. Figure 2 illustrates the planning process for an STD program. It should be noted that monitoring and resource mobilization are continuing activities.

Situational assessment

The objective of assessment is to obtain a clear picture of the STD situation in a country, the resources available for STD control and the political, legal and social factors that might influence the program. This information is required to set priorities,

Figure 2
STEPS IN PROGRAM PLANNING



decide on strategies and plan implementation. The assessment should be **rapid,** and as much information as possible should be collected from existing sources *(see Chapter 15).*

Information is needed on STD epidemiology, existing services, available resources, health-seeking behavior, patient knowledge, attitudes and perceptions of STDs *(see Chapter 13),* and factors influencing program development and implementation. Sources of information for a rapid assessment are the following:

Key informants. Ministry, district and municipal health and administrative officials; NGO staff; public and private health-care providers; target populations

Documents. Laws and regulations; Ministry of Health plans and reports; national HIV/AIDS plan; job descriptions of health-care staff; clinic and laboratory records

Publications. Scientific publications on prior STD research; publications on studies in neighboring countries; and it is worth noting that some of the most useful sources of information are often unpublished.

Epidemiology of STD

To set control program priorities and direct interventions at groups most likely to become infected with STD, managers should ask the following epidemiological questions:

- Which clinical syndromes are most common?
- Which STD pathogens are most prevalent?
- What is the sensitivity of these pathogens to available antibiotics?
- Which populations are at greatest risk? And for each group, what is its approximate size and where is it located?

Based on the available epidemiological information, the initial estimate of the size of the STD problem will be used for two purposes. First, this information will help convince decision makers that STDs are indeed a serious problem in the country. Second, it will guide program managers in setting control program priorities.

Existing services

To make optimal use of existing resources, managers must assess the available sources of STD clinical care. These include the public sector—either through specialized STD facilities or general health facilities—the private sector and the informal sector. The latter includes pharmacists and untrained providers such as drug vendors. Nonallopathic medicine may be part of the formal system in countries where formalized training and registration of such practitioners exist, but in most countries such systems are considered informal.

As much as possible, the accessibility, acceptability and quality of private and informal sector care providers should be assessed to identify potential service provision partners and locate any weaknesses that

need to be addressed. For example, in countries in which a majority of STD patients prefer private practitioner care over government services, improving case management by private clinicians might be the most efficient way of controlling STD in a community. If most STD patients self-medicate, following the advice of a local pharmacist, a feasible approach might be to train pharmacists to take a simple history and sell drugs to treat the reported syndrome.

Available resources

The STD program manager should know what resources are available and whether additional resources are likely to be available in the future. For example, there might be donor interest in funding STD control activities, or a political commitment to STD control might lead to a reallocation of funds within the Ministry of Health.

In addition to financial resources, program managers should assess the available personnel, infrastructure, materials and drugs. Examples of resource assessments include:

- The staffing levels in a few representative rural and urban primary health-care (PHC) facilities or outpatient departments, which will indicate the available human resources
- The availability of appropriate STD drugs in health facilities, which will show whether drug logistics or drug policy constrains program implementation
- The physical structure of health facilities, which might need improvement in order to provide acceptable services
- The staffing level, equipment and operations of a university STD clinic, which might reveal an important resource for referral, training and research

Influencing factors

Finally, an STD program manager should be aware of the political, legal and cultural factors that influence STD control activities. Since these factors could significantly hinder the program, they should be confronted and, if possible, remedied. The following are examples of such constraints:

Political. Lack of political commitment, due either to lack of knowledge or fear of cultural sensitivities

Legal. A requirement that STD patients be reported by name, rather than by case, which drives STD patients underground; laws that do not allow non-physicians to prescribe antibiotics, even though they may be the sole health care providers at clinics; requirements that forbid sex workers from continuing to work for several days if an STD is identified, which keeps these women from seeking care

Cultural. Stigmatization of persons with STDs, especially women, leading to poor healthcare-seeking behavior and difficulties in partner notification; the community perception of STDs may be quite different from the medical perception and may lead to poor communication *(see Chapter 13.)*

Attempting to change political attitudes, laws, perceptions and cultural norms is a lengthy process. Nevertheless, identifying these factors is the first step.

Political Commitment

Unless a political commitment to STD control is obtained, only limited resources will be available for the program. Also, in most countries it will be difficult to promote safer sexual behavior, introduce sex education into the school curriculum or promote condom use without political commitment.

The preliminary estimate of the STD problem's severity, made from the situational assessment, often convinces policy and decision makers that they must take action. What also must be emphasized is the increased risk of HIV infection associated with STD. When possible, a calculation or estimate of the economic cost associated with STD should be made. This information will further advance the case that the STD problem has broad societal consequences.

The national STD committee, national medical associations, NGOs and other pressure groups can contribute to raising awareness of the STD problem, and they should be involved in advocacy of a commitment to STD control.

In countries in which STD control is a sensitive issue for cultural or religious reasons, it might not be possible to obtain political commitment immediately. But often a commitment can be achieved by demonstrating success. A successful intervention project, with quantitative information on the costs and the outcome, will in most instances convince decision makers that STD control activities are feasible and politically sound.

In other cases, an acceptable entry point can be used to place STD control on the public health agenda. For example, a congenital syphilis control program might be perceived as less politically threatening than an STD control program. As the program is being implemented, staff could collect information on levels of syphilis infection that could then be used to win support for a more comprehensive STD control program.

Developing a National STD Policy

A national STD policy stating the STD control program's strategies and approaches toward achieving its objectives puts the program in a formal framework. The policy statement shows the government's commitment to addressing the STD problem and provides clear policy guidelines as well.

For example, the following STD policy statement from India indicates a commitment to a primary healthcare approach to STD control:

> The Ministry of Health and Family Welfare strives to integrate comprehensive STD control efforts in the existing health care system, both public and private. Integration of comprehensive STD case management at the primary level of the health care system will receive special attention, so as to provide as much as possible nonstigmatizing services with a high level of accessibility and acceptance by the consumer. This will involve an emphasis on nonspecialized, integrated services. Principles of privacy and confidentiality, essential to the success

Box 2

Guidelines for Prioritizing STD Program Strategies

The following are the main criteria for deciding what strategies should be given highest priority:

Efficacy or the extent to which the strategy contributes to addressing the problem. Questions that should be asked are the following: How relevant is the strategy? What is the size of the population covered? What is the acceptability?

Example: Prevention is more relevant than provision of curative services. Yet prevention activities are usually accepted by a population only when curative health care needs are also being met.

Feasibility or the extent to which it is possible to implement the strategy. What financial, human and material resources are available? Are there political, cultural or legal constraints? How sustainable is the strategy?

Example: An intervention with sex workers will not be feasible if it leads to increased stigmatization and harassment by police. Similarly, condom promotion is still difficult in many countries because of religious, cultural and political sensitivities.

Efficiency or the extent to which the strategy is cost-effective. Which strategy makes optimal use of the available resources and delivers the highest yield for a given input?

Example: The syndromic approach to STD case management is more cost-effective than case management by specialists with laboratory confirmation of etiological diagnosis.[4]

of any attempt to deal with STDs, will strictly be adhered to. Cooperation from and collaboration with the private sector and NGOs will be promoted.[3]

Selection of Program Priorities

STDs and their complications are not evenly distributed throughout a population. To make optimal use of often scarce resources, managers should give priority to interventions targeting groups most likely to be affected by STD. These priorities should be based on the results of the epidemiological assessment.

Studies and key informant interviews will help managers identify groups of individuals with higher rates of infection than the general population. Since they can perpetuate an infection in a community, targeting groups such as symptomatic STD patients as well as those sometimes called the "core groups" should be a program's highest priority. However, care should be taken that such targeting does not lead to further stigmatization of these groups.

Most programs cannot reach all these groups at the same time. The following criteria can be used to set priorities:

- Estimated STD prevalence (or incidence) in the group
- Extent to which individuals in the group contribute to further transmission of STD (largely dictated by the estimated number of sex partners per individual for a given period of time)
- Size of the group
- Group awareness of the problem and interest in an intervention
- Feasibility of an intervention, based on geographical accessibility, acceptability and availability of resources

Other groups that should be targeted are those whose members frequently suffer STD complications, particularly women. In most societies women have little control over sexuality and limited access to STD care. In addition, they often suffer from asymptomatic or symptomatic infections that are not recognized as abnormal.

The group or groups targeted will influence the strategies and approaches chosen to meet program objectives. For example, in a society in which women with STD are easily stigmatized in STD clinics and outpatient departments, an effective strategy might be to integrate STD clinical services into MCH/FP clinics.

In setting program priorities, managers should choose the disease problems that are amenable to cure and that are associated with increased HIV transmission. Strategies that can be implemented easily without major investments in the health-care system should be selected.

Setting Objectives and Designing Strategies

There is often considerable confusion about the definition of these terms, yet a clear understanding of objectives and strategies is essential for effective program management.

Objectives

The general objectives of an STD control program state in broad terms what the program is expected to achieve. The three general objectives of STD control programs are listed in the introduction to this chapter. Specific objectives state in detail what is to be accomplished in a given period of time in order to make progress toward achieving the program's larger objectives. They should be formulated in the following way:

- The **outcome** expected from the intervention
- The **population** targeted by the intervention
- The **geographic or socioeconomic area** targeted by the intervention
- The **time frame** for reaching the stated outcome
- The **target** for the intervention

The target is usually expressed as a proportion of the target population in which an expected outcome is achieved. For example—

- **90 percent of STD patients** attending public facilities in the capital will be managed according to national diagnostic and treatment guidelines by the end of year two.

STD programs cannot be evaluated effectively unless specific objectives, including a statement of measurable targets, are clearly formulated *(see Chapter 14).*

Strategies and activities

A set of activities undertaken to meet a specific objective constitute a strategy. There may be one or more strategies implemented to meet an objective. The relationship between specific objectives, strategies and activities is illustrated in Box 3. A generic list of strategies and program activities for a typical STD control program is included in Appendix 1.

Designing strategies

Strategies need to be designed for the following program components:

- Behavior change communication (BCC) to promote safer sexual behavior, consistent and correct condom use, and appropriate health-care-seeking behavior
- Delivery of services for management of STD patients and their partners
- Condom programming

In this chapter the emphasis is on designing strategies for service delivery, which includes aspects of BCC and condom provision. These three components must be developed in a coordinated fashion. For example, if the BCC program recommends early treatment of STD, then such services should be available. Similarly, if condoms are promoted, they should be accessible.

A cornerstone of STD control is effective STD patient management. This includes diagnosis and treatment combined with individual counseling, health education, condom promotion and provision, and partner notification. Patient management is provided through clinical services, which should be **acceptable, accessible and effective.**[5]

In many countries the private sector is the most important provider of STD care. In these countries, strategies should be designed to make optimal use of available health-care providers. Initially, it is often difficult to involve the private sector, but training, referral services, continuing medical education, involvement in STD surveillance and perhaps access to laboratory services should all be considered to involve this sector.

Detection and treatment of asymptomatic infections is a special form of service delivery. An example of a cost-effective strategy for identifying asymptomatic

Box 3

Relationship Between STD Objective, Strategy and Activities

Specific objective for the STD control program:

By the end of year three, 90 percent of the newborns delivered in public health-care facilities in the country will receive prophylaxis for the prevention of ophthalmia neonatorum (ON).

Strategy:

- Provision of services for ON prophylaxis

Activities:

- Identify sites with maternity facilities.
- Assess the number of deliveries in identified sites.
- Train nursing staff in routine ON prophylaxis.
- Supply drugs to identified facilities.
- Supervise implementation and make corrections.

Box 4

Elements of Successful STD Service Delivery

A successful strategy for service delivery in most situations is one in which—

- Case management for the majority of the STD patients is integrated at first-level health-care facilities, using a syndrome-based approach to clinical management.
- Case management by the private and (where indicated) informal sectors is improved and strengthened.
- These services are supported by a limited number of specialized STD clinics providing referral services, training, research and monitoring.

infections is the screening of antenatal clinic attenders for syphilis.[6] The feasibility and cost-effectiveness of screening other groups depend on the availability of a sufficiently sensitive diagnostic method, its cost, and the prevalence of infection in the group.

Planning Implementation

After deciding on program priorities and strategies, the program manager must prepare a plan for implementing control activities. Planning and developing the three control program components (STD clinical services, BCC and condom programming) must be coordinated, regardless of the program's size and scope.

In addition, close coordination with the Essential Drugs Program (EDP) is important. This is to ensure that the appropriate STD drugs are on the country's essential drugs list and are made available to first-level health-care facilities. It is advisable to involve an EDP representative when preparing and regularly reviewing standard STD treatment guidelines.

If the plan is to provide STD case management for women through MCH/FP and antenatal clinics, the MCH/FP program should be involved early in the planning process. The feasibility, cost and implications of integrating STD and HIV/AIDS prevention and STD case management into MCH/FP programs can be assessed through an initial pilot project.

Available financial, human and physical resources must be considered when planning STD control. Often resource shortages will impose constraints on the program. For example, limited funds for staff trained in syndromic management will mean that program activities cannot be implemented countrywide.

It is often necessary to adopt a phased approach to program implementation. For example, a program could initially develop interventions in one or more urban areas where both high-risk behavior prevalence and STD incidence are high. Concurrently, additional research on the etiology of STD syndromes and on antibiotic susceptibility patterns could begin. In a later phase, services could be expanded to other urban settings and to rural areas as well. Specific quantifiable objectives and indicators for each phase of the program should be developed and clearly stated.

The crucial step in program planning is the preparation of a step-by-step work plan with a realistic timetable and budget. This plan can consist of two separate tables. The first lists the strategies and, under each strategy, the specific activities, with a timeline for implementation. The second table lists the strategies and activities, with budget estimates for each activity.

A work plan is an important **planning, budgeting and monitoring tool.** Detailed planning should only be done for the first year of the program, with an outline of the plan for subsequent years. Toward the end of the first year, a detailed plan for the next year should be prepared.

Planning for Support Components

The following support components are essential to developing and implementing an STD control program and should be included in the detailed work plan:

- Guidelines
- Training
- Logistics (including drugs and condoms)
- Laboratory services
- Research
- Surveillance

Although these components are discussed in other chapters of the handbook in greater detail, their management implications are described below.

Guidelines

Guidelines are used as a reminder and as an easy source of reference for health workers. They guide providers in adopting standard approaches to patient management. For example, national STD treatment guidelines will contribute to creating standardized STD treatment regimens. It is important that the STD program manager ensure that these guidelines are revised regularly to respond to changes in antibiotic resistance. Similarly, diagnostic guidelines can be revised when new and simpler tests become available.

Guidelines should be integrated into STD training and ongoing medical education for private sector practioners *(see Chapter 8).*

Training

Additional training for health-care workers is usually required when providing STD clinical care through first-level health-care facilities and adopting a syndrome-based approach. Target groups for such training are those providing STD case management, including medical officers, nurses, medical assistants, private practitioners and possibly informal or traditional health-care providers. Training should not be confined to hands-on providers alone, but should include a community's policy makers and opinion leaders.

Each member of an STD program team should be trained for his or her role in the program and should view that role as a link in the STD control chain. For example, a patient's first encounter may be with an orderly or registration clerk whose attitude toward the patient could influence the quality of the information that the patient later gives to the clinical staff. If the patient feels stigmatized or perceives a lack of confidentiality, the interview process may be counter-productive.

A program manager must ensure that training is both appropriate and effective. The training program must be based on an analysis and detailed description of the tasks and skills required of the various cadres of health workers. The training needs identified by this analysis form the basis for preparing training modules. To be effective, these modules should make use of interactive training methods and be clear and pragmatic.

In general, most training needs are in clinical diagnosis, including STD history-taking and physical examination, and in individual counseling and health education. Only limited emphasis should be placed on laboratory diagnosis of STD, except in situations where simple laboratory diagnostics are easily available. In many countries, particular attention needs to be paid to addressing negative and stigmatizing attitudes that some health workers have about STD patients.

Medical schools and other tertiary educational institutions in developing countries need to play a greater role in STD training for physicians and allied health providers such as nurses, laboratory workers, pharmacists and public health staff. These schools should take the lead in the didactic and practical aspects of such training as well as in course curricula design and development. An STD component should be an essential feature of the postgraduate medical training curricula in public health, obstetrics and gynecology, pediatrics, dermatology, epidemiology, microbiology and internal medicine *(see Chapter 6).*

Logistics

Failure to prescribe effective drugs and frequent drug shortages contribute considerably to low attendance rates at STD clinical facilities. An STD program manager should assess STD drug requirements and ensure that the drugs recommended in the national STD treatment guidelines are available. Ideally, the drugs should be included on the country's Essential Drugs List. Similarly, condom requirements should be assessed in health facilities where STD patients are managed *(see Chapter 5).*

The cost of STD drugs is a major constraint for many STD programs. Bulk purchase of drugs might facilitate price negotiations and reduce the cost to the program *(see Chapter 7).*

Laboratory services

Laboratory support services are usually absent or minimal at the peripheral and middle levels of the health care system. Consequently, patient management is based on history taking and clinical examination. Yet laboratory services are essential for an accurate assessment of STD epidemiology, including antimicrobial resistance patterns, and for detecting asymptomatic infections.

Managers should make it a priority to develop or strengthen at least one center where microbiological and epidemiological research on STD pathogens can

be performed. This center will provide the data on the relative prevalence of STD pathogens responsible for the various syndromes and antibiotic susceptibility, information that is needed for effective syndromic case management. Where resources permit, laboratory services can be gradually expanded, provided such services contribute to improved patient management *(see Chapter 12).*

Research

The program manager should include in the program's work plan operational research that will influence how a program is implemented. For example, studies on the prevalence of pathogens responsible for STD syndromes and on antibiotic resistance are important for formulating or adapting patient management guidelines. Results of research on the efficacy and cost-effectiveness of the syndromic approach will convince policy makers to support this strategy. And studies on the incidence and prevalence of STD in specific subgroups might lead to new priorities for the control program.

Other important operational research issues for STD programs include the following: identifying the most suitable ways of providing STD prevention and control through the primary health-care system; evaluating clinical algorithms for STD patient management; assessing the effectiveness of different methods of contact investigation; and conducting ethnographic research to gain a better understanding of health-seeking behavior and providers' attitudes toward STD clients. Such operational research is usually conducted by or in collaboration with a specialist STD clinic, a medical college or a university hospital.

Surveillance

Similarly, the results of STD surveillance should influence control program planning and implementation. Surveillance of antimicrobial sensitivity, the effectiveness of patient management approaches and the program's impact lead to important program management decisions *(see Chapter 15).*

Box 5

Resource Mobilization for an STD Program

Mobilizing resources for an STD program requires the following:

- A detailed, realistic work plan
- A clear statement of the size of the problem and the vulnerability of the problem to an intervention

It is easier to mobilize resources if the program manager can show the following:

- Success in previous program activities
- Success in using resources efficiently
- The cost-effectiveness of a program

Resource Mobilization

Mobilizing financial, human and material resources is an important step in the planning process. The situational assessment should have identified the resources available to the program and indicated the size of the STD problem. Thus, the initial assessment is an important tool for mobilizing additional resources from the Ministry of Health, donors and the private sector.

Although outside donors are an important source of support for many countries, the long-term sustainability of largely donor-funded programs should be considered. Most donors have their own requirements for the accounting of funds, and it is often advisable to employ an accountant to meet these requirements.

Resource mobilization requires frequent advocacy and negotiations with many sectors including national governments and international partners. Care should be taken that the program's absorptive capacity is not exceeded.

Monitoring and Evaluation

Monitoring

Monitoring is the process of assessing how well various program activities have been implemented *(for a more detailed discussion, see Chapter 14)*. It may be based on periodic field visits, regular activity reports and reports on special activities. Monitoring should be both quantitative (how much is being achieved) and qualitative (how well activities are being carried out). For example, it is not sufficient to know how many people have been trained in syndromic STD case management. It is also important to assess through observation and supervision how successful the training was in providing health workers with the skills they need in applying the syndromic approach.

Monitoring will reveal when and where the program falls short of what was expected. This knowledge allows program managers and implementers to identify constraints, which should lead to problem solving and adjustments. By using monitoring results to make corrections to the plan, program managers can ensure that resources are being used in the most efficient way.

Evaluation

Evaluation is defined as a periodic assessment of whether a program is meeting its planned objectives. Typically, programs are evaluated at one or two-year intervals. Planning for evaluation is an integral part of program planning and should be done at the start of the process.

Although evaluation might make use of information collected through monitoring activities, in most cases it will require a special survey or study. Sometimes, a survey will also be needed to establish a baseline against which progress can be measured. For example, a specific objective "to reduce STD prevalence among sex workers by 50 percent in one year" requires both an initial cross-sectional STD prevalence survey and a follow-up survey after one year to evaluate the intervention's impact.

Revising or Planning for Program Expansion

Evaluation results are essential to revising less successful program components, planning program expansion, or developing and implementing new strategies.

To revise the program plan, managers might need to reformulate objectives or design new strategies for meeting program objectives. Planning program expansion involves the same steps as those described earlier. In both cases, a new work plan with a budget and a timeline should be developed.

CONCLUSION

Managers of STD control programs are responsible for ensuring that program resources—human, material or financial—are used in the most cost-effective way to reach the program's stated objectives.

To fulfill this responsibility, managers must assess the available resources, the infrastructure and the extent of the STD problem. They must prioritize the strategies and activities that are most likely to achieve the program's objectives cost-effectively. Carrying out these strategies and activities requires a detailed work plan with a realistic timeline and budget. A work plan's implementation must be monitored against set targets, and an evaluation will reveal how successful the program has been in reaching its stated objectives.

This chapter has outlined essential aspects of program management and described in detail the planning process. This process will allow program managers to develop cost-effective STD control programs that are sufficiently flexible to accommodate social, cultural, epidemiological and political variations and to make the greatest use of existing resources.

APPENDIX 1

GUIDELINES FOR STD CONTROL PROGRAMS

1. Strengthen program management

1.1 Develop/strengthen central STD unit
- Assess staff needs.
- Employ staff and/or train existing staff.
- Develop coordination mechanisms with the Information, Education and Communication Division.

1.2 Develop/strengthen regional/district STD management structure
- Assess available human resources.
- Organize STD planning and management workshops.
- Develop communication mechanism with central unit.
- Monitor activities.
- Plan supervisory visits.

1.3 Establish STD Advisory Committee
- Identify members of the STD Advisory Committee.
- Organize regular meeting of the committee.
- Communicate results of meetings to decision makers.

1.4 Develop a national STD control policy and strategy.

2. Strengthen STD case management

2.1 Design flowcharts
- Organize a national meeting to design patient management guidelines, including flowcharts.
- Field test the flowcharts in pilot areas and adapt them.
- Finalize, print and distribute flowcharts.
- Review flowcharts every two or three years.

2.2 Strengthen case management in public sector
- Conduct an inventory of facilities.
- Assess needs in equipment and consumables.
- Assess training needs.
- Estimate STD drug and condom needs.
- Develop or adapt training module.
- Train trainers.
- Schedule further training of health workers.
- Purchase and distribute equipment and consumables.
- Develop drug logistics.
- Provide training in stock management.
- Monitor clinic use and clinical practices.
- Plan refresher training.
- Develop or adapt training module.
- Organize training workshops.
- Monitor clinical practices.
- Plan refresher training.

2.3 Strengthen private sector case management
- Invlove national private medical association(s).
- Conduct an inventory of private health-care providers.
- Assess clinical practices and training needs.
- Develop or adapt training module.
- Organize training workshops.
- Monitor clinical practices.
- Plan refresher training.

2.4 Improve STD service provision to women
- Pilot test integration of STD services in MCH/FP clinics.
- Assess feasibility and cost.
- Expand STD service provision at other sites.

2.5 Strengthen national reference laboratory
- Assess needs in equipment and consumables.
- Assess training needs.
- Purchase equipment and consumables.
- Develop or adapt STD bench-level laboratory manual.
- Train laboratory technicians.
- Monitor activities.

2.6 Control of congenital syphilis
- Conduct an inventory of antenatal clinics (ANCs).
- Estimate the number of attenders in ANCs.
- Identify laboratory support (either in or linked to the ANCs).
- Assess equipment and consumable needs.
- Purchase and distribute equipment and consumables, including syphilis serological tests (RPR or VDRL).
- Institute screening of all ANC attenders at first visit (if possible, also in the third trimester).
- Treat women and partners testing positive.
- Develop reporting mechanism.
- Monitor activities.

2.7 Prophylaxis of ophthalmia neonatorum (ON)
- Conduct an inventory of facilities with maternity facilities.
- Estimate the number of deliveries in maternity facilities.
- Purchase and distribute prophylactic drugs.
- Train health-care staff in the application of prophylaxis.
- Implement ON prophylaxis of all newborns.
- Train traditional birth attendants (TBAs).
- Provide TBAs with prophylactic drugs.
- Monitor activities.

2.8 Targeted interventions for high-risk groups (core groups)
- Identify target groups.
- Develop access to target groups through key members.
- Design services to meet needs of each group.
- Train health providers and peer educators for treatment and outreach.
- Develop a reporting mechanism.
- Monitor activities.

3. Promote prevention and treatment-seeking through Information, Education and Communication (IEC)

3.1 IEC through mass media
- Identify and define priority groups.
- Identify community leaders.
- Assess knowledge of priority groups.
- Define appropriate channels of communication.
- Develop messages and materials with members of the target groups.
- Pretest, develop and print IEC materials.
- Monitor IEC activities.

3.2 IEC through outreach (peer) educators
- Identify priority groups for outreach work.
- Conduct qualitative research on knowledge and practices (risk behaviors, health-care-seeking behavior).
- Identify peer educators.
- Develop and/or adapt appropriate materials.
- Train peer educators.
- Monitor peer education activities.

3.3 IEC through traditional media (theater, music, etc.)
- Identify traditional channels of communication.
- Develop training materials.
- Orient and train traditional artists.
- Review productions.
- Monitor activities.

4. Establish condom programming for STD prevention

4.1 Distribute condoms through treatment facilities
- Identify facilities providing STD services.
- Estimate condom needs.
- Purchase condoms and develop distribution system.
- Train health workers in condom promotion and demonstration.
- Include condom distribution in STD patient management.
- Monitor condom distribution activities.
- Monitor condom quality.

4.2 Social marketing of condoms
- Identify social marketing organizations and/or NGOs.
- Assess condom needs.
- Develop a condom distribution network.
- Monitor condom sales.

5. Monitor STDs

- Organize a national workshop to develop an STD sentinel surveillance protocol.
- Develop training module for STD surveillance.
- Select sentinel sites and conduct training.
- Supply sites with required equipment and supplies.
- Analyze data and communicate results.

6. Conduct operational research

- Define research priorities.
- Identify research sites and/or facilities.
- Assess needs (equipment, consumables, training).
- Provide resources.
- Train staff.
- Collect results and communicate to interested parties.
- Modify the program according to the results.

7. Evaluate

- Plan program evaluation.
- Compile results and inform interested parties.
- Organize a meeting with program managers and decision makers.
- Organize planning to revise or expand program.

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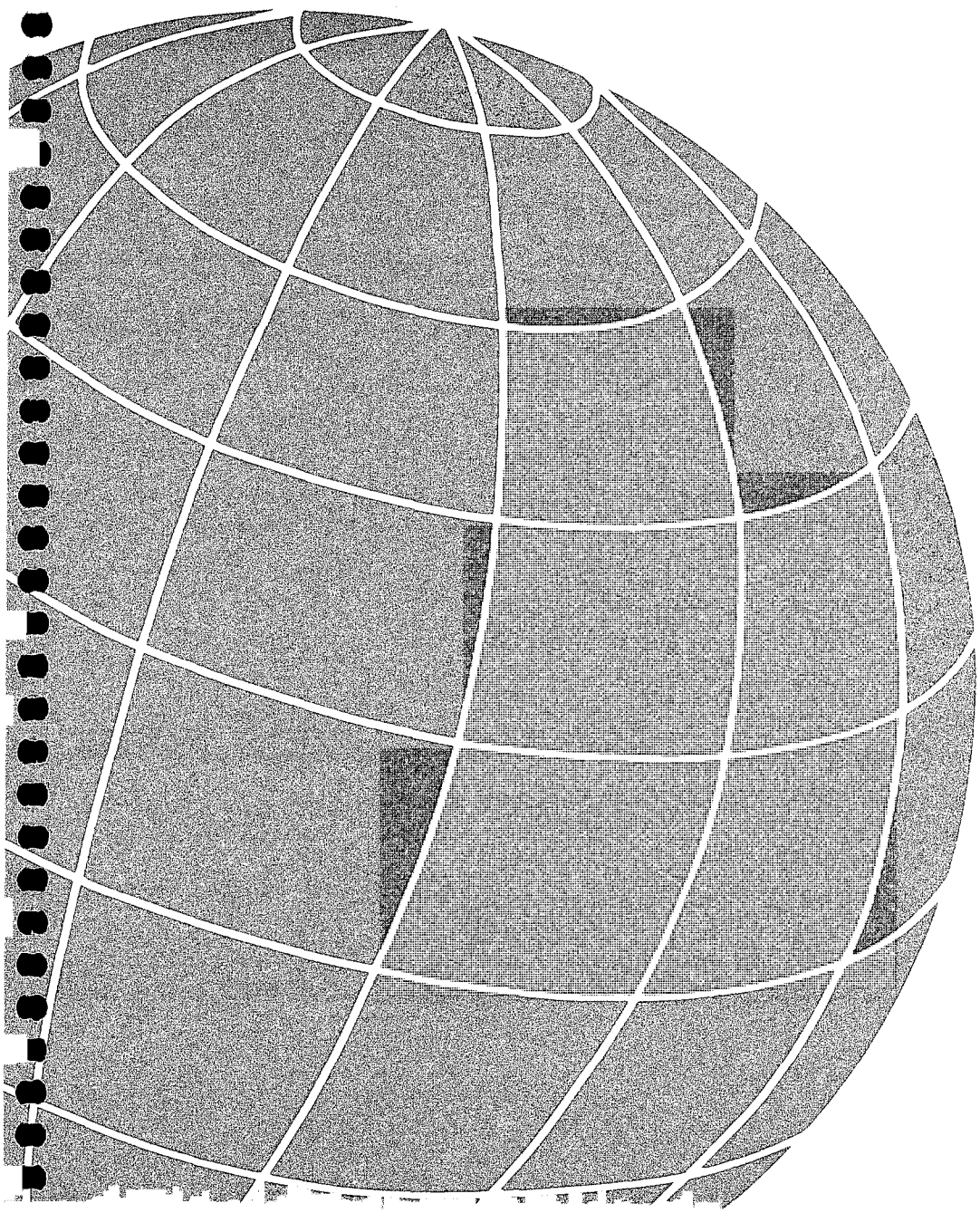
C H A P T E R 3



Issues in Integration of STD Programs into Health-care Systems

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preview CHAPTER 3

Issues in Integration of STD Programs into Health Care Systems

INTRODUCTION

This chapter provides a strategy for the integration of STD prevention and care activities into health care systems. The focus is on the circumstances needed for implementation and when it is necessary to add specialized approaches as well.

AN OVERVIEW OF CURRENT STD DELIVERY SYSTEMS

Existing STD programs have not been very effective in increasing access and improving cost-effectiveness. The reasons include:

- Absence of a rational STD package
- Low priority by authorities
- Uncoordinated STD service delivery
- Specialized STD Treatment Facilities
- STD case management in primary health care: horizontal approach
- Private sector providers

COMPELLING NEED FOR A NEW APPROACH

The appearance of HIV and AIDS, the pandemic of its fatal complication, have led to an urgent reappraisal of current STD control. Deficiencies must be addressed and strategies must be developed that transcend the limitations of past efforts. A six-step approach is proposed to change public attitudes about STDs, create a lower level of STD incidence and reduce STD complications.

INTEGRATION

An integrated approach proposes decentralized operational structure but with a central national unit responsible for research, technical guidance and materials. The focus of STD management would be at the district level.

LESSONS LEARNED FROM CASE STUDIES

- Strengthening Prevention and Management of STD/AIDS, Kenya
- The District STD Intervention Program in Mwanza Region, Tanzania
- Improving STD Case Management in the Jamaican Private Sector

INTRODUCTION

This chapter describes a strategy for planning and implementing the integration of STD prevention and care activities into health-care systems. First, an overview of integration issues is presented. Second, current practices in STD service delivery and the disappointing results of different approaches to STD case management, including prevention, are discussed. Third, an integrated approach is described using the example of the district as the place where integrated services can be organized and implemented. (By a district we mean the most peripheral administrative area with some form of local government or administration where many responsibilities have been taken over from central government sectors.)[1] The focus is on the circumstances under which implementation can occur and where additional specialized approaches may still be needed. Finally, case studies are presented of small-scale integrated approaches that have shown early successes.

Over the past few decades, governments, health experts and care providers have used the word "integration" with a variety of meanings and in different situations. For some, integration may mean a new organizational structure merging various disease control programs. This may result in the fear that integration will bring a dilution of specific efforts in a system already too bureaucratic, and lead to endless delays in decision making at all levels. Those who have this fear believe instead that integration should mean regular coordination through information sharing among decision makers of existing programs.

Another view is that integration means adding tasks to unqualified and already overburdened staff, which leads to poor delivery of services. Those who share this fear argue that integration ought to mean a sharing of resources such as transportation among different programs.

Both views fail to appreciate that the aim of integrating specific disease control efforts is to enable the overall health program to provide appropriate services to more people at an early stage of disease development. This should be done in an environment in which educational and clinical activities can take place, referrals can be ensured, and patients can feel at ease. To achieve such an ambitious outcome, much more than coordination and sharing of resources is needed. Integration in this sense means that all health-care programs are responsible for and provide STD care as long as STDs remain a priority.

Integration of STD services into a decentralized and strengthened district health-care system is being proposed as an approach at the implementation level.The underlying principle of integration is a **sharing of responsibilities** by programs, units or departments and moreover by people involved in implementing health care at all levels.[2] Through such sharing of responsibility, broader access to STD prevention and care services can be achieved in an environment where stigmatization can be minimized,[3] earlier access to services facilitated and easier continuation of services guaranteed. In addition, cost-effectiveness is enhanced through the provision of **better** services **closer** to those in need by **more** providers.

AN OVERVIEW OF CURRENT STD DELIVERY SYSTEMS

So far the existing STD programs have not been very effective in increasing access and improving cost-effectiveness. Reasons for this lack of success are outlined below.

Absence of a Rational STD Package

As a result of the lack of authoritative guidance on a rational, practical and well-defined standard package of activities for STD prevention and care programs, the following has occurred at the implementation level:

- Little or no emphasis has been put on reducing risk behavior, preventing further infections and notifying partners
- Although resistance has developed widely to low-cost microbial agents, programs continue to use these antibiotics because they are available and inexpensive
- STD control efforts have concentrated on treating symptomatic patients (usually men) and have failed to identify asymptomatically infected individuals (often women) until complications occur.

Low Priority by Authorities

Donors and policy makers give low priority to allocating resources to strengthen STD control because of a lack of confidence in the effectiveness of health services. Other reasons for this low priority include:

- The association of STD with discreditable/immoral behavior
- Failure to associate STDs with their complications and sequelae
- Failure to recognize the magnitude of the problem

Uncoordinated STD Service Delivery

STD services have often been delivered through specialized public or private STD treatment facilities (clinics) that provide inadequate coverage at high costs and contribute to stigmatization, particularly for women. Existing public, traditional and primary health-care (PHC) facilities have so far failed to provide a first level of effective care with appropriate referrals because of poor management, inadequate support and lack of sensitivity to STD clients' needs.

Specialized STD Treatment Facilities

In some countries, STD control is based on the belief that only categorical or special STD clinics can provide the necessary quality case management. Examples of these model STD clinics can usually be found in towns or cities, often located in major hospitals or affiliated with university hospitals. Physicians with specialized training are meant to provide care for patients referred because of complications or particular difficulties, but in reality see mostly first-contact patients.

Usually these programs are highly centrally organized and coordinated from a special unit in the ministry that takes full responsibility for implementing national STD control activities. Financial management, supplies, drug distribution systems, training plans, staff allocation, and reporting and supervisory systems are all directly controlled by the central unit. These specialized clinics are particularly well suited to offer training opportunities in STD case management.

Quality of medical care provided is usually high but very staff- and resource-oriented. These types of STD programs tend to promote their own parallel organizational structure by establishing a system of special clinics to reach the more peripheral levels of the health-care system. For example, within such a program at the district level, one can find STD outpatient

clinics with special staff, supplies and records. Because these clinics are easily identifiable, stigmatization of clients is common.

In the past, governments, funding agencies and donors have promoted such a vertical approach for a variety of reasons. Many believe that this approach results in more efficient case management. Another reason, however, is that centralized control and tight accountability of how finances are spent enables governmental and nongovernmental organizations to satisfy donor demands to link expenditures with specific measurable outcomes.

The advantages and disadvantages of this vertical approach are summarized in Table 1.

STD Case Management in Primary Health Care: Horizontal Approach

In programs where STD case management is integrated into primary health care, a first outpatient contact between a care provider and an STD care seeker can result in direct STD case management, leading to high coverage. STDs can be diagnosed and treated at any level or site of the public health system, be it a village dispensary, a health center, a maternal and child health (MCH) or family planning (FP) site, or an outpatient clinic at any hospital. General health-care providers with their basic training and sometimes with refresher STD training can provide treatment for uncomplicated cases of discharges and genital ulcer diseases. Only complicated conditions need to be referred.

Laboratory support is requested from the existing laboratory system at that site. The quality of care, including the use of available essential drugs and laboratory support, is supervised by the local clinician responsible for that site. At the national level, technical guidance and coordination can be provided by the units responsible for peripheral health-care services and

Table 1

Specialized STD Clinics: Vertical Approach

Advantages

Referral possibilities
Any network of special centers with properly trained staff and the necessary drugs and equipment can provide quality clinical care for complicated cases.

Training opportunities
On-site in-service training can provide experience with a wide range of clinical conditions and management approaches.

Monitoring and research
These STD centers also offer opportunities for epidemiological and clinical studies on etiology, drug efficacy and antimicrobial susceptibility.

Accountability
Effective financial control and accountability from central to peripheral levels can be facilitated through an STD-specific management information system, particularly when the general health services have difficulties functioning adequately.

Disadvantages

Clinical orientation
The technical expertise in a vertical program gives it a strong clinical orientation. Integration with health promotion activities is by definition structurally absent. Therefore, emphasis on the education necessary to prevent transmission (condom promotion and partner notification) is usually limited.

Cost
Establishing and maintaining parallel distribution and supply lines and separate infrastructures with full-time, specially trained personnel is very expensive.

Inadequate availability
Special clinics cannot provide quality services to all in need of STD care. Most STD clinics are in urban areas, depriving large, rural communities of care.

Inadequate access due to stigmatization
Segregating STD care from other health services contributes to stigmatization of STD clinic clients and the tendency to blame them for their disease. Staff attitudes have often enhanced these perceptions, which has led to reduced accessibility, particularly for women.

Low sustainability
The sustainability of vertical programs is vulnerable because responsibilities for a centrally organized vertical program lie with a few individuals, and continuous supervision and supplies depend on a separate organization and distribution system.

essential drug supplies. This approach is often promoted under the programmatic umbrella of primary health care.

Although this horizontal approach offers the potential for improved access, prevention and cost-effectiveness, its implementation by Ministries of Health (MOHs) has suffered. This is due to several setbacks resulting from the overall decline in socioeconomic development in many parts of the developed and developing world. In addition, over the last 10 years very few funding agencies or bilateral donors have committed themselves to assisting MOHs in improving overall health infrastructures and supporting operating costs. As a result, district and peripheral health staff are demoralized, unsupervised and underpaid. Facilities are not maintained properly and essential drugs and other supplies are not regularly available.

Since diagnostic supplies and available antibiotics often do not match the need for STD treatment, confidence in the health system is lost, attendance drops and alternative services are used. In particular, unaccredited providers with poor training or no training at all have filled the demand gap. Inadequate treatment has resulted in the development of drug resistance and disease sequelae. In addition, these alternative services place no emphasis on prevention.

Private Sector Providers

In addition to specialized and integrated government programs, other sectors provide much—if not most—of STD care. These private providers may operate officially (licensed) or as unlicensed practitioners *(see Table 2)*. Both are widely accepted and utilized.

In order to improve the quality of STD services, the private sector should not be ignored. In many countries, it provides a significant amount of STD care, although the care is often inadequate or inappropriate in clinical aspects and, in particular, lacks the emphasis on preventive aspects. The challenge for STD control programs is to ensure that coordination occurs with the official providers and that patients are diverted from unlicensed providers.

Table 2
Sources of STD Care

Public government sector

- Specialized, categorical or dermato-venereology clinics
- Outpatient departments (OPDs) of other specialties in hospitals
- First-level care, including emergency rooms, general outpatient departments, health centers, dispensaries, MCH and FP clinics, and village health posts

Private official providers

- Private STD clinics
- OPDs of private hospitals
- Private physicians, including general practitioners and various specialists (dermatologists, gynecologists, urologists)
- Pharmacists (where it is legal to dispense antibiotics without prescription)
- Nonprofit nongovernmental organizations (NGOs) and mission hospitals through first-level health care, hospital OPDs or specialized clinics

Private unofficial providers

- Traditional healers who use alternative or herbal treatments
- Traditional healers providing antibiotics
- Pharmacists (where it is illegal to dispense antibiotics without prescriptian)
- Untrained medical practitioners
- Street vendors

COMPELLING NEED FOR A NEW APPROACH

STD incidence in the world is unacceptably high as a result of ineffective treatment and limited STD prevention and care activities. In practice STD prevention and care often consist of a quick STD history taking and a prescription for treatment. As a result, most care givers miss the opportunity to help prevent further transmission.

The rapid appearance of a new sexually transmitted infection, the human immunodeficiency virus (HIV), and the pandemic of its fatal complication, acquired immune deficiency syndrome (AIDS), have led to an even more urgent reappraisal of current STD control. Early STD disease detection by health staff and appropriate treatment can substantially reduce STD incidence and prevalence, and also lower the risk of transmitting or acquiring HIV.

To address these deficiencies, an appropriate intervention would include:

- Promoting health-care-seeking behavior directed particularly toward those at increased risk of acquiring STD, including HIV infection *(see Chapter 13)*
- Providing rational diagnosis and effective treatment for curable symptomatic and asymptomatic patients with STD and their partners *(see Chapters 8 and 11)*
- Promoting safer sexual behavior, including condom use *(see Chapter 10)*
- Providing condoms at affordable prices *(see Chapter 5)*

To translate these objectives into a practical, feasible program, one would aim for broad community acceptance. Ideally, this program would be part of community health services, which would offer this package of preventive and curative measures. The implementation steps for a new approach to STD intervention, which will be provided by *all* care providers and serve *all* in need, are shown in Figure 1.

These first three steps should be combined as an intervention package. A training module should be developed and workshops organized to teach PHC staff at the district level how to use a syndromic flow chart. In addition, sufficient refresher materials and wall charts should be left behind in each PHC facility.

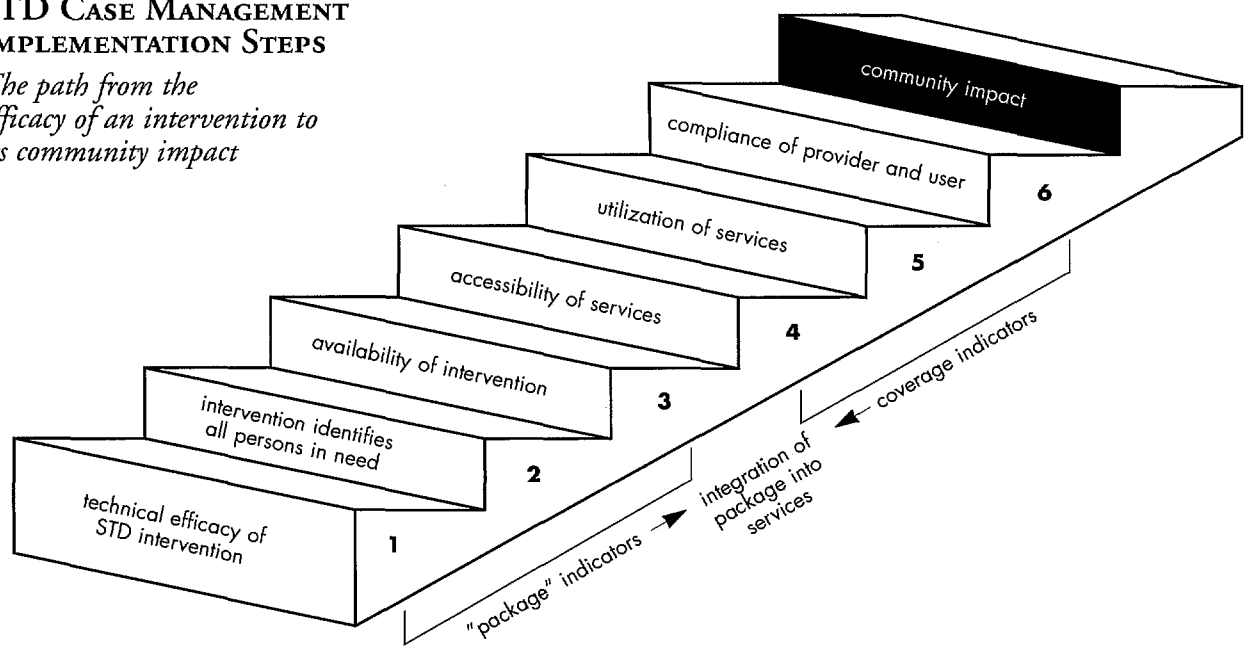
- **Step 1.** An effective intervention would use the syndromic STD approach described in Chapter 8 (technical efficacy of STD intervention).
- **Step 2.** People with STDs need to be aware of the importance of early treatment and be able to recognize their symptoms in order to seek health care. Clinicians need the diagnostic and communication skills to make decisions based on flow charts of syndromic approaches (identification of all persons in need).
- **Step 3.** To apply a syndromic approach, clinicians need the appropriate flow charts and a regular supply of drugs, as well as referral possibilities (availability of intervention).

Steps four through six aim to extend the coverage of health services by ensuring that when people recognize symptoms, they will come to a health facility promptly, possessing the confidence that the facility's staff members have been able to build.

- **Step 4.** The syndromic approach should be integrated into a care system that is easily accessible to those in need. Accessible means both affordable and conveniently located (accessibility of services).
- **Step 5.** Health services must be accepted and liked by men and women in the community. This is particularly important for STDs, because feelings of stigmatization are common. Well-organized services and positive attitudes among staff members will ensure that services are used (utilization of services).
- **Step 6.** Committed care providers should emphasize the need for adherence to a full treatment course and continuing care, including partner notification and proper follow-up (compliance of provider and user).

If all these steps are given adequate attention in the implementation process, a successful community health impact could be expected. This approach can lead to a reduction in STD complications or even a reduction in STD incidence within the community using the health-care facility. If implementors focus on only one or two steps but not on the whole process, a positive impact on the health of community members is very unlikely (step 7, community impact). Process indicators can be identified for each step in order to

Figure 1
STD Case Management Implementation Steps
The path from the efficacy of an intervention to its community impact



measure the progress made at regular intervals, such as every three months. These indicators form the base of the monitoring system for the services.[4]

INTEGRATION

In order to reach the largest possible population in need, these interventions must be offered at sites that are easily accessible to patients. In providing both prevention and care interventions on-site, an appropriate balance between face-to-face educational and clinical activities will have to be maintained. Coverage and quality are thus the cornerstones of this integrated approach to STD care and prevention. This emphasis is designed to avoid the pitfalls of current practices and boost confidence in the STD services.

Key elements of one such integrated approach would include:

- Shared responsibility by all health-care providers, particularly at the district level
- A decentralized operational structure that gives district health teams the authority and means to coordinate and supervise the STD prevention and care activities of public and nongovernmental providers
- Syndromic diagnosis at first-level contact based on a "package" standardized through in-service training of all health-care providers
- A strong emphasis on face-to-face education during any contact
- A cost-effective approach to service delivery through cost-recovery measures

The strengths and weaknesses of the steps in STD case management implementation for each of the various existing approaches to STD case management are

Table 3

Comparison of STD Delivery Systems

[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
Technical efficacy of STD care intervention	++	−−	+	−	+
Appropriate clinical and educational mix within the intervention	−	−	+−	−	+−
Intervention identifies all men and women in need	−−	+	−	−	+
Availability of intervention drugs/ supplies/condoms	+	−	+	+−	++
Accessibility of facilities/services	−−	++	+	++	+
Services/facilities utilized	−	−	+	++	+
Compliance and sustained provision of services	−	++	+	+−	+

compared in Table 3. This comparison illustrates how the proposed integrated approach could result in strengthened comprehensive care management and wider coverage.

With this decentralized, integrated approach, a central national unit responsible for developing training materials, ensuring technical guidance and initiating relevant research would be maintained. Specific referral sites would be developed encompassing STD clinical expertise, training and research.

The focus of STD management would be at the district level, where a district health management team consisting of public and nongovernmental health planners and managers would be responsible for coordinating STD prevention and care. This team would ensure quality control at all relevant contact points for people in need of STD services, such as hospital outpatient clinics, MCH/FP clinics, dispensaries and health centers. If such a management team were strengthened and had the authority to operate, it would then be feasible to maintain close contacts with private sector providers to guide them on comprehensive approaches and initiate relevant in-service training. These would include:

- Seminars through local medical associations to improve knowledge and skills in STD management
- The sharing of guidelines
- A centralized lab used by both public and private sectors
- Linkages to condom programs
- Referral services
- Pharmacy training

LESSONS LEARNED FROM CASE STUDIES

Box 5

Strengthening Prevention and Management Of STD/AIDS, Kenya

An STD care and prevention project that started at a single clinic in Nairobi in 1991 has been expanded to cover several communities in two cities and is being adopted by the Ministry of Health and several NGOs for nationwide implementation. The initiative is a collaborative effort involving the University of Nairobi, Kenya's Ministry of Health and the University of Manitoba, Canada.

What has been done

All health workers involved in outpatient and MCH care at several sites have been trained, and adequate, continuous drug supply and supervision have been ensured. Integrated, decentralized STD services, including syphilis screening for antenatal women and syndromic case management, are provided at these sites. Face-to-face education is linked with clinical care.

Coverage has been extended through special educational activities to promote self-awareness of symptoms and early health care seeking among vulnerable groups such as truck drivers, partners of STD patients, and sex workers and their clients.

Communities within the catchment area of all program clinics have been motivated to promote education to people at risk for STD/HIV transmission through regular public meetings, formation of health committees and identification of peer leaders. This community action has strengthened early health care seeking and improved coverage.

Lessons learned so far

A new approach is feasible as long as there is a continuous stimulus through supervision. Constraints to scaling up the activities are:

Organizational: Managing the increased workload, maintaining refresher training and a timely referral system, and ensuring a continuous drug supply.

Coverage: Ensuring that the real first contact between a pregnant woman and a provider includes a screening for syphilis and necessary education.

Education: Ensuring that education works, in particular for symptomatic males, and empowering women to negotiate safer sex.

Experience with the program to date suggests that through community involvement and improved services, progress can be made toward reducing risky sexual behavior and increasing condom use.

Source: Dr. Elizabeth Ngugi and Dr. Stephen Moses

Box 6

The District STD Intervention Program in Mwanza Region, Tanzania

As part of an intervention study on the impact of improved STD services on HIV transmission, Regional Medical Services of Mwanza, Tanzania, in cooperation with the African Medical and Research Foundation (AMREF), has implemented an STD control program in several areas of the region since December 1991.

What has been done

STD services are fully implemented through the existing PHC structure, using all outpatient services at dispensaries and health centers, in 29 communities.

The intervention consists of four essential components: training of health workers; supply of effective drugs; regular supervision; and health education.

Health workers (nurses, rural medical aides, medical assistants) from PHC units are invited to a one-week training course at the regional center. To allow the effective management of STDs in the absence of laboratory facilities, trainees learn to treat STDs syndromically, using simple flowcharts. Classroom teaching is followed by two weeks of practical training at the regional STD reference clinic. The regional STD intervention officer and a female health educator then approach the key groups in the communities, raising awareness and providing information and education on the importance of early STD care and the need for STD prevention.

Health workers return to their villages equipped with effective drugs, and supervision is provided monthly by district staff who offer in-service training and supervision for the PHC workers. Training and supervision are designed to enable district health services to run the program on its own. Health education campaigns in the communities are repeated intermittently. Staff members collect data on treatment outcomes and antibiotic consumption to monitor the program.

Lessons learned so far

While most health workers will participate in this intervention without additional compensation, some demand allowances for the extra work. Duties are performed well in general, but condom promotion and health education of individual STD patients are not always adequate, often because of the heavy workload at these units. The difficult economic situation of the country in general and of health workers in particular poses the main obstacle to the program's success. Workers sometimes sell drugs to increase their incomes.

Patients have accepted the program, sometimes with great enthusiasm, particularly when they were cured after long-standing illnesses. However, a survey revealed that about 20 percent of the men and 30 percent of the women still sought STD treatment elsewhere, often from drug sellers in neighboring villages and from traditional healers. Lack of confidence in the formal system and the stigma attached to STDs must still be overcome. *(Editor's note: The results of this study, which were published in August 1995, show a reduction in the number of new HIV infections occurring over the two years of the study by 42 percent.)*[5]

Source: Dr. H. Grosskurth, AMREF, Mwanza

Box 7

Improving STD Case Management in the Jamaican Private Sector

In Jamaica, private clinicians traditionally have managed an estimated 50% to 60% of all STDs in the country. Through the Medical Association of Jamaica, STD case management was introduced using a continuing medical education format. The goal was to improve private sector STD case management and encourage cooperation, including case reporting, between the public and private sectors.

What was done

Through a collaborative effort involving the Medical Association of Jamaica, the Jamaican Ministry of Health and USAID's AIDS Control and Prevention (AIDSCAP) Project, seminars were organized on the following topics: Urethritis, genital ulcer disease, HIV, vaginal discharge, and STDs in infants and children. A practical, public health-oriented, syndromic approach to STD management was emphasized. State-of-the-art data and diagnostic approaches were also presented to address the academic interests of the audience as well as their access as private practitioners to additional diagnostic tests. Targeting mostly private sector health-care providers, including nurse practitioners, each seminar was repeated in three geographic locations and included national and international speakers. Summary review articles were written and published in the local medical journal. Relevant journal articles and book chapters were provided to all participants.

Immediately prior to each seminar, written pre-tests were administered that included self-reported case management questions. They were repeated in telephone interviews one to three months following each seminar. Based on these data, inappropriate choice of penicillin to treat gonorrhea decreased from 43% to 4%. Adding tetracycline to gonorrhea treatment increased from 59% to 81%. Treating genital ulcers with co-therapy for syphilis and chancroid increased from 68% to 83%. Sexual risk reduction counseling increased from 84% to 93%, and counseling regarding partner notification and treatment increased from 59% to 64%.

Lessons learned so far

Seminars through medical organizations offer an effective strategy to improve the quality of STD care among physicians in the private sector.

Cooperation between public and private sectors in this manner may improve reporting.

Public health oriented practices such as counseling for partner notification and treatment may require additional interventions to be successfully incorporated into the private sector.

Source: Dr. M. Green, Medical Association of Jamaica, Kingston, Jamaica

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C H A P T E R 4

An Approach to Effective Communication

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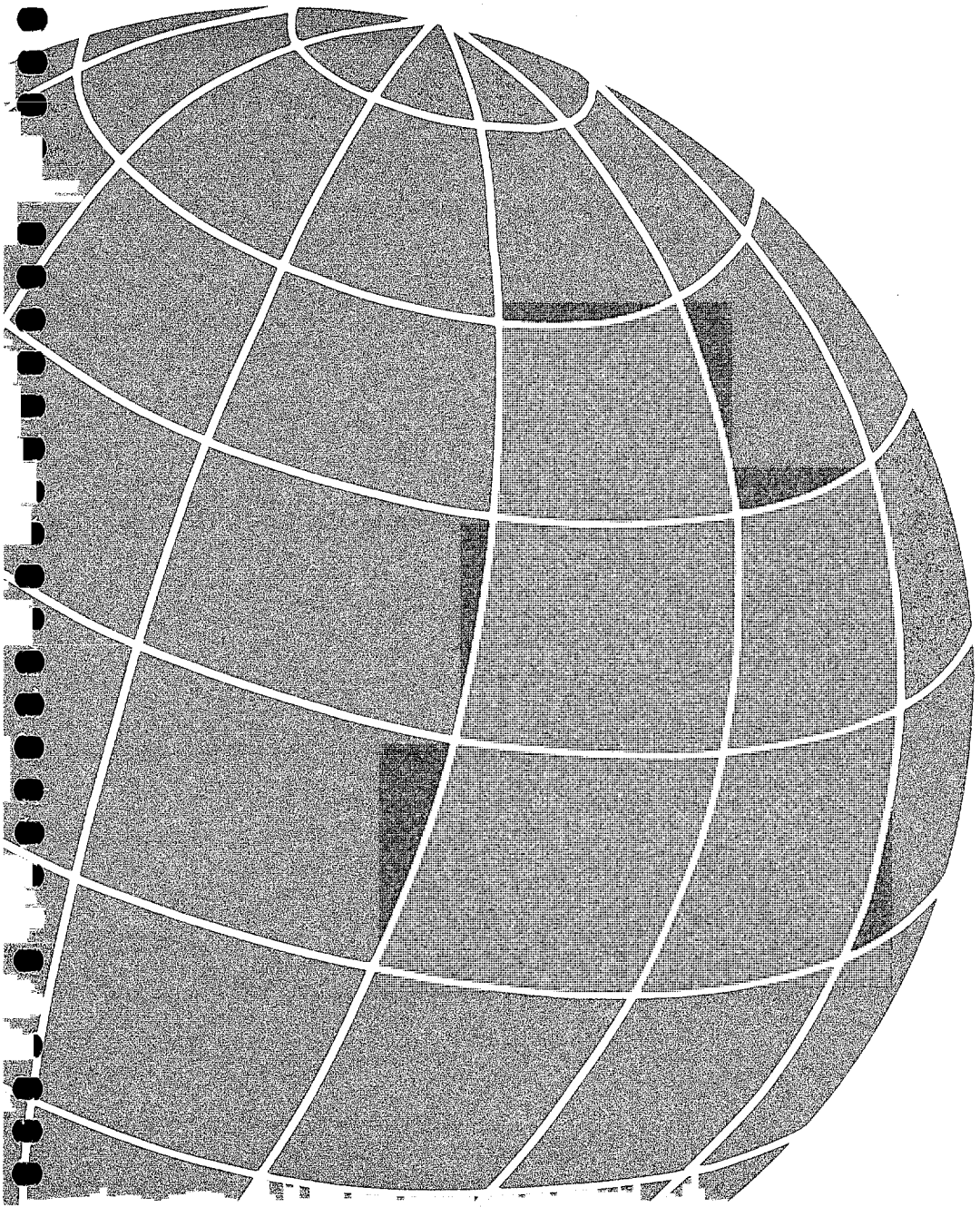

preview CHAPTER 4

An Approach to Effective Communication

INTRODUCTION

This chapter addresses communication strategies aimed at altering behavior in order to prevent infection.

HISTORICAL PERSPECTIVE ON STD MESSAGES

In the past, some campaigns have had limited impact because of their use of scapegoats and moral judgments to convince people to change their behavior.

USING MEDIA TO DELIVER STD MESSAGES

The strength of mass media lies in their ability to convey information to a large population that leads to knowledge and an understanding of a problem or issue; interpersonal channels, on the other hand, are effective in changing attitudes and behavior.

COMMUNICATION AND BEHAVIOR CHANGE THEORY

Communications programs that are creative and effective need to be based on behavior change theory, sound public health practice and well-designed audience research. Personal or untested methods of changing behavior are not adequate substitutes.

CONTEMPORARY MARKETING PRINCIPLES

Communications programs should draw upon contemporary marketing principles to create effective programs. The principles include:

- Audience Segmentation
- Audience Research
- Concept Development and Pre-testing
- Accessibility of product

STRATEGIES FOR REACHING PEOPLE WITH MESSAGES ABOUT STDS

An effective communications plan includes the following action-based steps:

- Defining the Problem (situation analysis)
- Setting the Objectives
- Identifying the Target Audience(s)
- Developing Key Messages
- Selecting Channels of Communication
- Pre-testing Messages/Materials
- Producing and Disseminating
- Implementing the Program
- Evaluating the Results
- Receiving Feedback to Improve Communication

CONCLUSION

Research and proper planning form the foundation of an effective communication campaign. Knowing the needs of the population and the best means of reaching that audience are crucial in achieving the goal of raising awareness and, ultimately, changing attitudes and behaviors.

INTRODUCTION

The cornerstone of STD management and prevention programs is the clinical setting. These clinic-based programs are extremely important *(see Chapter 10)* in providing treatment and information to eliminate future infections. However, most STD prevention education and communication opportunities exist outside the clinical setting. Unfortunately, in the past these efforts have been extremely limited.

This chapter provides a framework for expanding the role of communication to include preventing infections, and early detection and treatment of existing infections. It is designed to help STD clinic or program managers by providing a theoretical structure and process for developing effective behavior change communication.

Since approaches to interpersonal communication are described in detail in the chapter on patient education *(see Chapter 10),* they will not be emphasized here. Instead, the chapter will emphasize the use of mass (for instance, radio) and small (for instance, pamphlets) media to reach people outside of the clinical setting. However, the effectiveness of most interventions will be significantly strengthened when they combine these with interpersonal communication, which is particularly effective in influencing changes in attitudes and behavior.

The chapter begins with a historical overview of STD communication. Later, there is a review of behavior change theories and, subsequently, a practical process is offered for developing communication strategies to reach people with prevention messages. At the end of the chapter, there is

a list of additional resources for more in-depth study of communication.

For additional communication assistance and support, the program manager is encouraged to identify and contact local resources. These include advertising or public relations agencies, universities, professional writers and editors, and other communication experts in health departments or nongovernmental organizations (NGOs).

HISTORICAL PERSPECTIVE ON STD MESSAGES

Most STD communication efforts have been based on the clinical treatment model. While a number of media-based programs have been implemented worldwide, their messages have had a limited effect. Often messages have been fear-based and have not provided relevant incentives for target audiences to change behavior. Some messages have stigmatized certain groups and given false confidence to others, who inferred that they were not at risk of contracting STDs.

For example, during World War I the U.S. military implemented an extensive communication program to prevent and control venereal disease (VD). This "social hygiene" campaign used fear-based messages that targeted women as the cause of VD, such as: "Women who solicit soldiers for immoral purposes are usually disease spreaders and friends of the enemy."[1]

Despite the general lack of effectiveness of these messages, a World War II campaign against VD continued to focus on women as the source of disease with pamphlets and posters entitled "She Looked Clean But...." In campaign posters, VD was often depicted as a woman, and "loose" women were characterized as a threat to soldiers.[1]

These campaigns also spread a message of moral judgment against those who contracted VD. In an effort to escape detection, many individuals did not seek medical care, often turning to home remedies. The powerful stigma associated with VD was reinforced through mass media efforts, further limiting both the public's and medical profession's ability to effectively respond to the disease.[1]

PREVENTION MESSAGES

Messages for prevention of STDs include the following:

- Encourage individuals to use latex condoms consistently and correctly every time they have sex.
- Encourage individuals to practice other safer sex behaviors, e.g., forms of non-penetrative sex.
- Encourage individuals to abstain from or delay sexual intercourse.
- Encourage people to reduce their number of sexual partners.

Early detection and treatment efforts can be strengthened by communications that accomplish the following:

- Increase awareness of types and prevalence of STDs.
- Help individuals recognize signs and symptoms.
- Encourage individuals to seek without delay medical care from a biomedical provider especially if signs or symptoms are present.

These detection and treatment efforts can be further improved by messages that:

- Reinforce prevention behaviors among people already infected with STDs.
- Encourage people infected with a sexually acquired infection to notify their partners and refer them for treatment.

COMMUNICATION AND BEHAVIOR CHANGE THEORY

Developing communication programs is both an art and a science. To help ensure that communication efforts are effective, programs should be based upon behavior change theory, sound public health practice and well-designed audience research combined with creative communication strategies.

Too often, program planners develop communication strategies based on personal or untested assumptions about what leads to behavior change, and not upon clearly articulated theories of behavior change and communication. Planners often assume that providing factual disease information alone will lead individuals to change behavior. Others discard this assumption, but replace it with an equally untested belief that communicating about potential health benefits will bring about behavior change. In most cases, messages based on either assumption will not result in the desired behavior change, although both approaches may be useful in increasing a target population's knowledge. Behavioral scientists often refer to the disparity between knowledge gained and behavior changed as the "knowledge-behavior gap."

Several behavior change theories and communication hypotheses have been developed to explain and bridge the gap. Although consensus has not been reached on adopting a single approach, several theories have proved useful in explaining the factors that influence behavior. These determinants of behavior, including attitudes and beliefs, social norms, religious values and socioeconomic status, often vary from culture to culture. It is important to identify determinants of behavior based on the cultures of each country and the targeted communities within a country.

An overview of a model for behavior change and a model for developing effective communication is presented in the next two sections.

THE AIDS RISK REDUCTION MODEL

The AIDS Risk Reduction Model, which was developed to provide a framework for changing behavior known to increase the risk of contracting HIV infection, is also directly applicable to risky behavior that can lead to STD transmission.[2] This model is based on the premise that to avoid disease, individuals must perceive that their sexual behavior places them at risk for HIV infection (labeling); make a commitment to behavioral change (commitment); and take action to change (enactment).

Labeling is influenced by perceived susceptibility, knowledge of HIV transmission and perceived norms regarding sexual behavior.

Commitment is influenced by the perceived costs and benefits of high-risk versus low-risk behavior.

Enactment is influenced by social support, skills in developing health behaviors and perceived norms.

STAGES OF CHANGE MODEL

Prochaska suggests that sustained behavior change occurs after an individual has moved through the stages described in Box 1.[3] While these stages may not accurately describe the behavior change process in all situations or different cultures, they do suggest a strategic framework for developing communication programs.

These stages suggest that information dissemination alone does not constitute an effective prevention program. Enhanced awareness and knowledge of health risks are important preconditions for change; however, knowledge in and of itself has never proved the chief motivator for change. The model also demonstrates that a program that starts with skills (e.g., how to use a condom) before individuals accept that they may be at risk is also likely to fail.

Box 1

STAGES OF CHANGE

An individual...

- is unaware of problem.
- becomes aware of problem.
- is concerned that behavior places him or her at risk.
- acquires knowledge about the problem.
- is motivated to act through perceived risks and benefits.
- is ready for action through skills acquired to enact change.
- tries new behavior.
- assesses the efficacy of changing behavior and, if successful
- sustains behavior change.

In summary, in order for their behavior to change, individuals must perceive the following:

- They are at **personal risk**
- Changing their behavior will **result in benefits** that are relevant to them
- **social norms** will support their actions at each stage of behavioral change
- they have the **skills and resources** needed to make the changes

CONTEMPORARY MARKETING PRINCIPLES

A behavior change communication program should also draw upon contemporary marketing principles. The most consistently effective of these is targeting campaigns to carefully selected segments of a larger audience. Audience segmentation is based on selected variables such as demographics (e.g., age and gender), health status (STD- or HIV-positive), geographic dispersion and values. Targeting allows planners to select appropriate messages, message sources and channels for each audience segment.

Social marketing, defined as the integration of communication and marketing techniques to change behavior, provides a sound framework for creating effective communication programs.

The following outlines social marketing principles:

- Segmenting the target audience by variables including age, sex, socioeconomic levels, psychographics (i.e., attitudes, values, outlook)
- Audience research to assess attitudes, perceptions, knowledge and behavior
- Concept development and pretesting to ensure that communication strategies and materials are effective and relevant
- Messages targeting various segments of the audience, because one message rarely moves everyone
- Communication that offers benefits meaningful to the audience
- Accessibility to needed products and services (e.g., latex condoms, STD diagnosis and treatment) through local commercial and non-commercial outlets

The close relationship between social marketing and efforts to sell commercial products is intentional. According to a leading expert, "the more a social change campaign resembles a commercial product campaign, the more successful it is likely to be."[4] The key is to

determine the needs and desires of the audience, then deliver message and products that offer real benefits. Many social change campaigns fail because the message is not meaningful or relevant and consequently not motivating to members of the target audience.

The following section outlines a framework for developing effective strategies in order to reach people with messages about STDs. It is based on the contributions from many disciplines including social marketing, mass communication, health education and the social sciences.

STRATEGIES FOR REACHING PEOPLE WITH MESSAGES ABOUT STDS

In order to reach people with messages about STD prevention, a communication plan should be developed[5] that includes the following action-based steps:

1. Defining the problem (situation analysis)
2. Setting the objectives
3. Identifying the target audience
4. Developing key messages
5. Selecting channels of communication
6. Pretesting messages/materials
7. Producing and disseminating
8. Implementing the program
9. Evaluating the results
10. Receiving feedback to improve communication

These steps are described in greater detail below.

1. *Defining the Problem (Situation Analysis)*

An assessment of the available data on the prevalence, type and rate of transmission of STDs is instrumental to understanding the problem and what needs to be done about it. Information about social, cultural, economic and political factors is also important in understanding the environment that provides the context for behavior change.

Organizations and individuals who control locally available resources and services need to be identified because they could have influence over the availability of products and services related to STD prevention and control. Their decisions and actions could determine whether: adequate quantities of drugs, condoms and other supplies are available; antibiotics can be purchased over the counter for STD treatment; educational materials are available in local languages to facilitate comprehension; STD prevention and condom promotion messages can be advertised through print and broadcast media; and, staff are trained to provide patient education and counseling.

Information should also be collected on the sexual practices and norms of the population to identify specific attitudes or behaviors that may help or hinder behavior change. For example, data could be collected on the prevalence of condom use versus the number of unprotected sexual exposures, and the types of sexual behaviors that might promote the spread of STD. This information might be available from the results of an overall program assessment or from anthropological studies conducted in the area. If not, it could be collected through focus group discussions, in-depth interviews, KABP (knowledge, attitudes, beliefs and practices) surveys or mini-surveys. Other key questions to consider include the following:

- Which community is most affected by this problem?
- What programs and services are currently addressing the problem and how effectively?
- What other external factors (e.g., religious) may affect how the problem will need to be addressed?

2. *Setting the Objectives*

The objectives of an STD communication strategy should be clear, time-specific, measurable and attainable. They should contribute to the overall program goals and be achievable with in-country resources (identified in the situation analysis).

First, the desired change or changes must be identified:

- A change in knowledge, behavior or attitude?
- A change in the level of knowledge about STD transmission, prevention or treatment?
- Increase in the number of trained STD counselors or workers skilled in providing health education to clients?
- Increased condom access and use?
- Fewer repeat STD cases?
- Improved STD referrals and partner notification?

The following are examples of objectives:

1. After a discussion with an STD counselor, 80 percent of clinic attendees can demonstrate comprehension of STD treatment messages by explaining correctly in their own words (a) why it is important to take a full course of treatment, and (b) why partner treatment is necessary.
2. STD messages will be illustrated in seven newly designed and pretested posters in six appropriate languages and distributed to all health posts and private clinics in the country by April.

3. *Identifying the Target Audience*

Target audiences are groups of people who have common characteristics related to disease transmission and control. The purpose of segmenting a large, general audience into smaller, more focused target groups is to develop specific messages that are relevant to the needs of each particular group.[6]

Targeted primary audiences may include groups such as adolescents, commercial sex workers (CSWs), military personnel, factory workers, transport workers and drug users. Other groups commonly targeted for STD and HIV/AIDS prevention programs are health care workers and teachers who can be intermediaries to primary audiences.

Group characteristics tend to be identified by the following:

- High-risk behaviors, such as those of people with multiple sex partners, men who have sex with men, people who engage in commercial sex activities or who share drug-using paraphernalia
- Demographic factors such as age, sex, occupation, location, level of education and income
- Psychographics (attitudes, values, outlook)
- Ethnicity, language and sexual orientation
- Organizational or institutional structures, such as health care facilities, factories, churches, cooperatives, school systems, prisons and the military

4. *Developing Key Messages*

Below are examples of questions that program planners can ask in order to learn more about the members of a particular target audience. The answers to these questions will help planners design more relevant, applicable and effective STD prevention messages and dissemination strategies for influencing this group.

1. What do members of this target audience know about STDs?
2. What are their concerns about STDs?
3. What behaviors put them at risk for STDs?
4. What do they do to avoid infection from STDs?
5. Do language, literacy and/or cultural barriers exist that need to be overcome?
6. What are some of their common attitudes about how STDs are acquired?
7. What are the special needs of this group?
8. Who are the leaders or who has influence in this group?

In addition to quantitative research (surveys), qualitative research (focus groups and interviews) can help answer key questions about a target group. Focus groups and interviews are effective methods for developing appropriate messages and for pre-testing program materials.

Led by trained moderators, about six to ten people, who are typical of the target audience, have structured discussions. Moderators use a set of open-ended questions to promote discussion about the subject matter as well as participants' thoughts, feelings, values and beliefs. A variety of possible messages are identified from these discussions, and three to five of the most important messages are selected for emphasis.

Presenting a few key messages at a time gives audience members a sense of confidence as they learn new things. The messages chosen should help target audiences understand the group-specific benefits of following health-promoting recommendations. For example, the advantages of using a condom might be valuable to a group of commercial sex workers (CSWs) for different reasons than for a group of adolescents. Focus group studies have shown that CSWs are more interested in condoms because it reduces their contact with seminal fluid and the need for frequent washing and douching. On the other hand, school age adolescents fear pregnancy and, outside of abstinence, see condoms as a way of ensuring that they will be able to complete their studies.

A thorough understanding of audience attitudes and beliefs and careful pre-testing are essential to ensuring that messages are effective. For example, in some cultures acquiring gonorrhea is a sign that a young boy has become a man. Messages to increase condom use in such cultures might be more effective if, rather than emphasizing the fact that condoms can prevent gonorrhea, they emphasize other benefits. These might include protection against STDs that can cause infertility, produce unhealthy babies or require costly diagnosis and treatment.

Careful attention should be paid to message development to ensure that messages are not misinterpreted or lead to unintended results. In some situations, efforts to reduce STDs with messages discouraging vaginal intercourse have resulted in increases in anal infections among young girls. This illustrates the importance of research and an understanding of the attitudes, knowledge and practices of the target group for the purpose of designing messages that lead to beneficial outcomes.

5. *Selecting Channels of Communication*

The choice of communication channels will depend on many factors, including the program objectives and the target audience's access to and preference for a particular channel. For example, the mass media are very effective in promoting a general understanding of a problem or issue, whereas interpersonal channels are effective in changing specific and individual attitudes and behavior. Mass media can be used to broaden the reach and impact of STD prevention and control. Clinic-based interpersonal interventions can be used to counsel patients about behaviors that cause STDs, promote the use of latex condoms and other safer sex practices, identify the symptoms of STDs and provide available treatments.

The following are information channels that are suitable for delivering STD messages:

- **Mass media** including television, radio, films, videotapes, drama, music, billboards, music, newspapers and magazines. Within these formats, messages can be embedded in the story lines of radio, TV, film, music and dramas; or STD awareness can be raised through news coverage or through clinic advertisements in a newspaper, etc.
- **Small media** including pamphlets, posters, flip charts, displays, models, T-shirts, matchbooks, hats, stickers, booklets and audiocassettes. Some of these channels are used to provide information (e.g., pamphlets, booklets), and others are used to remind people of earlier learning and previous decisions (e.g., T-shirts, stickers). They are complementary sources of information that help keep the STD issue on both private and public agendas.
- **Institutional and interpersonal networks** including schools, factories, youth clubs, women's groups, unions, professional associations, religious organizations, social groups, families, etc. Information disseminated through these groups by peer educators or by visiting "experts" can be very influential in supporting people to make risk behavior changes.

- **Health service delivery systems** including patient education programs in clinics; public health nurses; HIV counseling and testing centers; and condom distribution centers. In addition, in some cases pharmacies can be effective channels through which to deliver STD prevention messages.
- **Peer education** is an approach that can be considered a channel or an intervention. Messages disseminated among peers often have more credibility, immediacy and impact than more formal and distant channels. Peer educators have worked successfully among truck drivers, adolescents, CSWs, men who have sex with men, athletes, university students, health workers, teachers, military recruits and informal groups such as clinic attenders, taxi passengers and bar patrons.

Program planners should use several channels to reinforce STD prevention messages. To illustrate, a person reads an article about the consequences of STDs in the newspaper. Then he hears a radio advertisement about STD diagnosis and treatment, discusses it with a friend and calls a telephone hotline to find out more. Next, the individual goes to a clinic, picks up an informational leaflet in the waiting room and talks to a counselor before deciding to get tested.

In this illustration, the comprehensive communication campaign focused on a variety of channels including newspapers, radio, peers, a hotline, leaflets and counseling. For a real impact on knowledge, attitudes and behaviors, multiple exposures to prevention messages are needed.

Another example further illustrates this concept. A video dealing with sexuality could be viewed by a group of young people. Then, there could be a group discussion about key issues raised by the program, followed by role-playing exercises. Similarly, a radio talk show could be designed to stimulate interaction with the audience by encouraging listeners to telephone the radio station and ask questions. As media formats continue to evolve, there are an increasing number of opportunities to include media with interpersonal communications.

Approaches that involve peer-based community education, reinforced by media and institutional interventions, are especially effective in changing attitudes and social norms and in teaching new behaviors. Decisions about which channels of communication to "mix and match" should be based on their ability to inform, motivate and support the target audience's change toward STD preventive behavior.

6. *Pre-testing Messages/Materials*

It is important to give members of the target audience an opportunity to respond to message concepts, materials and delivery formats before they are finalized. This helps to ensure that the proposed channels are appropriate and that the messages are understandable to those they are intended to reach. Pre-testing and resulting adaptations may need to be done several times before the materials are truly effective.

The content and delivery of messages can be pretested through individual interviews or focus groups. The person conducting the interview or focus group should ask "open-ended" questions that probe for more information, and should avoid leading questions that might influence participants' responses.

Examples of pre-test questions:

1) What is this message telling you?
2) Is this important to you? Why or why not?
3) Who do you think should hear these messages? Where, how?
4) What do you like/dislike about the messages/ materials?

While one person conducts the focus group or interview, an observer should record what people say and how they react. These notes will be useful during an analysis of the results.

In pre-testing, it is important to get responses to content and presentation, including the format, color(s), style and other design elements of materials or other media. The text and images used in print materials should be pre-tested separately to identify any problems specific to either component.

The results of this participant pretesting should provide the basis for any changes in messages, materials and/or delivery methods. Although one or two comments may not reflect the thoughts or feelings of an entire target audience, messages and materials should be revised and tested again if a considerable number of pre-test participants find them incomprehensible, irrelevant or unacceptable.

7. *Producing and Disseminating*

Now that you know what you want to say and how it should be said, you are ready for production. Regardless of whether you decide to record a song for play on the radio, print a brochure or organize a theater troupe to travel across the country, you must invest in the actual "production" of the product to be distributed.

Depending on the product, persons skilled in producing it (writers, artists, singers, actors, printers, advertisers, etc.) will need to be hired and arrangements made to use their services. You will need to know if there is a fee for these services.

When the final product is ready, you must market and distribute it. Too often, well-designed and pretested messages and materials are not effectively disseminated to the target audience. What are the best locations for placing messages/materials in order to reach the target audience? Select the ones where audience members gather. For example, this may include bars, stores, markets, places of worship, clinics, worksites, etc.

Find out whose permission is needed to gain access to these places and approach them by telephone or letter. Distribution should be coordinated with the assistance of community leaders and other influential individuals and groups. Because this facet of the communication process requires the cooperation or participation of many people, it is essential to involve them throughout the process of developing the communication strategy. It is important to build these partnerships from the very beginning of the communication plan. In addition to extending the reach and credibility of the program, it will increase the likelihood that the community leaders will be supportive during the critical distribution phase.

If you have made a careful assessment of your resources during the first step of this process (see "Defining the Problem (Situation Analysis)"), you will be prepared to successfully carry out the distribution of the materials. Consider contacting private and non-governmental organizations that work with the same target audience, as well as religious institutions, social/cultural groups, professional organizations, labor unions, schools, universities, newspapers, television and radio stations. Ask yourself if any of these groups/individuals need special training to use the materials. Attention to this detail at this stage may prevent costly and valuable materials, guidebooks, videos, etc., from being stored on the shelf or in a warehouse and not properly used.

8. *Implementing the Program*

A multi-dimensional, comprehensive STD prevention campaign will have a more powerful and long-lasting impact than a single exposure, one-dimensional approach. A well-planned communication strategy will schedule complementary and mutually reinforcing activities at appropriate intervals. To increase the program's effectiveness, when creating an overall strategy it's useful to include other program components such as one-on-one counseling, partner notification and provider training events.

Make sure that the communication campaign is carefully coordinated with the rest of the program. If the campaign is promoting something that can't be delivered, this could have a negative effect on the STD prevention goals. For example, a communication campaign designed to increase the number of STD clients would need to be matched by the clinic's ability to handle an increased client load. Are staff members trained and available in sufficient numbers to provide services? Are there sufficient supplies (condoms, etc.) to meet the new demand?

It is important to capitalize on opportunities provided by different parts of the STD prevention program. Publicizing a training event, for example, could offer an opportunity for print, radio and television media coverage, including interviews with prominent participants. This, in turn, becomes an opportunity to inform audiences about the STD program. To take full advantage of this event, a campaign to increase awareness about the importance of partner notification or to introduce new STD treatments could be launched at the same time.

9. *Evaluating the Results*

Evaluation is frequently cited at the end of the communication process, but it should be built into the communication program as it is being designed. Based on key questions, evaluation helps determine whether and how well the project is achieving its goals and objectives. Has the campaign resulted in people changing their attitudes, behaviors and practices?

In assessing the effectiveness of a communication campaign, there are three basic types of evaluation: process, outcome and impact. Each of these has its own set of questions.

Process examines the steps involved in implementing the program (e.g., the number of people who were reached).

The following are possible indicators:

- Print coverage and estimated readership
- Number of educational materials distributed
- Number of speeches/presentations and audience sizes
- Number of other organizational and professional contacts

Outcome describes the immediate effects of the program (e.g., who responded to the STD prevention campaign).

Consider the following:

- Knowledge gained and attitudes changed
- Short-term behavior shifts
- Policy or other institutional changes

Impact, the most comprehensive, focuses on the long-range effects of the program (e.g., whether STD incidence was reduced as a result of the program). Consider the following:

- Changes in morbidity and mortality
- Long-term maintenance of desired behavior
- Rates of recidivism

10. *Receiving Feedback to Improve Communication*

The answers to the questions in the previous section will help identify the project's strengths and weaknesses. As shown in the examples below, "mid-course corrections" can be made to improve the activities and increase the likelihood of their success. Any changes should be communicated to the audience.

- If staff members report that no one is using the clinic, the facility may have to change its hours to accommodate the needs of its key audiences. Audience members should be made aware of the new schedule.
- If people are not taking the educational materials provided, the distribution methods should be assessed. Are they left in conspicuous places? Are they available where the key audiences congregate? Should they be distributed personally by the health care providers or by peers? Are people too embarrassed to be seen with them? Would a new design be more appealing or attractive?
- If clients are not coming back for follow-up visits, do the health care providers need more training in counseling, patient education or interpersonal skills?
- If nurses are too busy for one-on-one counseling, can group counseling be implemented; are peer counseling sessions a reasonable alternative?

Answering such questions early in the project will lead to refinement of the communication strategies and increase the effectiveness of the overall program.

CONCLUSION

If properly planned and implemented, communication programs both within and outside of the clinic setting can make an important contribution to STD prevention and control activities. In the past several decades, strategies were based on personal beliefs or moral judgments. More recently, however, strategies have been developed within thoughtful frameworks containing key communication elements that will lead to more successful results.

It is important to keep the following in mind:

- Effective communication campaigns are based on audience research combined with creative approaches to reaching those audiences.
- Behavior change models such as the AIDS Risk Reduction Model provide a consistent point of view for communication aimed at changing behavior that contributes to STD transmission.
- Messages can be delivered through a variety of communication channels, but the available channels must be carefully analyzed during the planning stages to determine which will be most effective in reaching target audiences.
- Social marketing techniques can be used to "sell" the idea of behavior change for prevention and/or treatment of STDs.

Communication campaigns for STD control and prevention need not rely on expensive materials or the latest in technological innovations to be successful. There are many options available to produce the desired goal of changing behavior. Above all, the complex tasks of addressing an issue as sensitive as STDs and promoting changes in behaviors that are often deeply ingrained and personal must be approached with a comprehensive, systematic plan that maximizes impact.

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CHAPTER 5

Condoms

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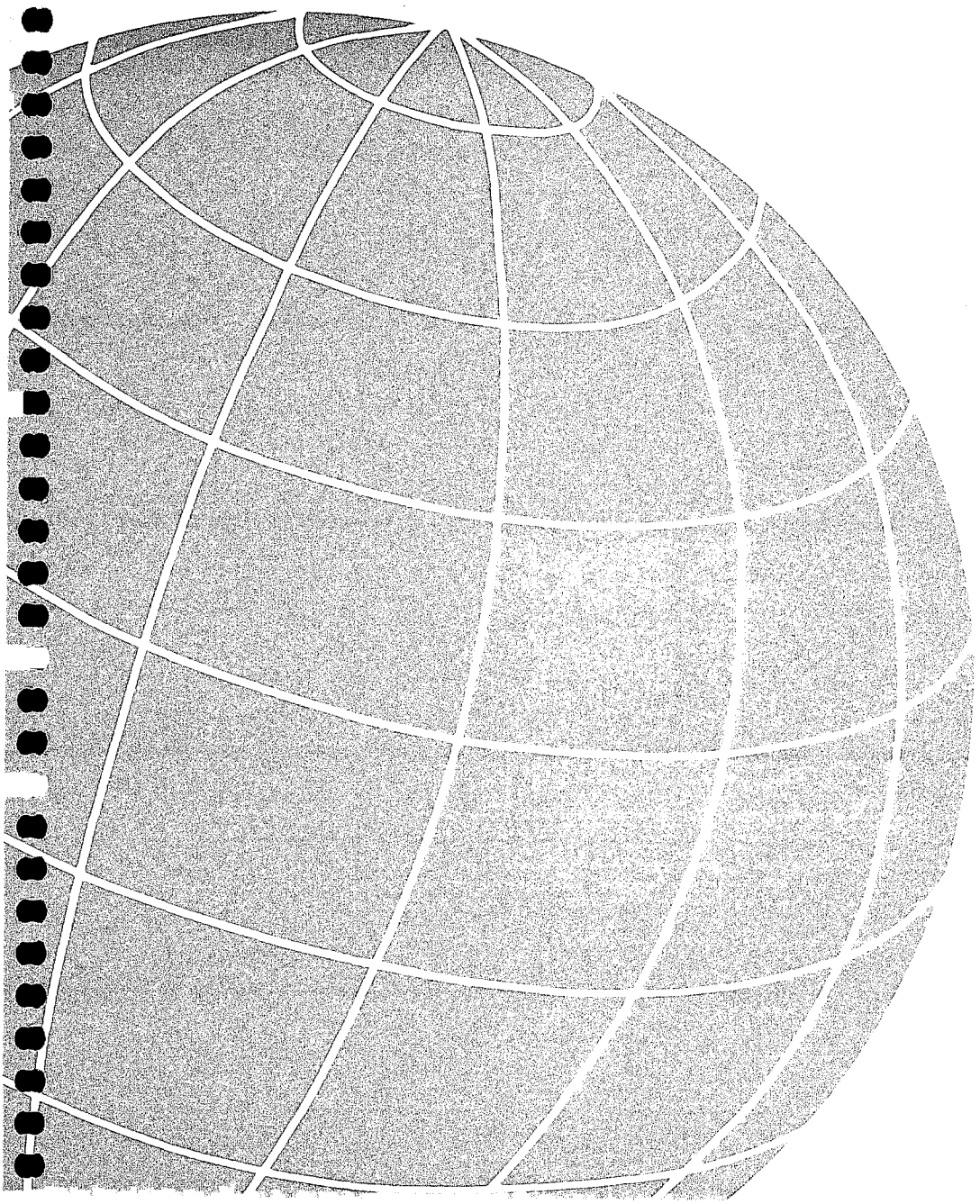


preview CHAPTER 5

Condoms

INTRODUCTION

This chapter addresses the following issues:

- Efficacy and effectiveness of the male latex condom
- Improving condom promotion and access
- Condom logistics management
- Other barrier contraceptives including spermicides, female condoms, male plastic condoms, vaginal sponges and diaphragms

EFFICACY AND EFFECTIVENESS OF THE MALE LATEX CONDOM

- Laboratory studies indicate that sperm and disease-causing organisms do not pass through latex condoms.
- Epidemiolgic studies in human populations indicate that STDs enhance HIV transmission, but that the correct use of latex condoms reduces the risk of contracting STD/HIV.
- Other factors influencing effectiveness include failure to use a condom correctly, condom slippage, use of an oil-based lubricant and insufficient vaginal lubrication.

IMPROVING CONDOM PROMOTION AND ACCESS

For STD case management, condom promotion is a three-pronged effort that includes the following:

- Condom education and counseling
- Condom skill building
- Condom distribution

CONSTRAINTS AND OPPORTUNITIES

Ignorance and myths contribute to constraints on consistent and correct condom use. Clinic staff members who foster a positive attitude about using condoms correctly can help to diminish client anxiety.

Condom promotion:

Public sector

- Clinic-based services can be expanded by ensuring that all health center staff are involved as much as possible in condom promotion and distribution.
- Clinic linkages to family planning and maternal/child health (MCH) programs can provide additional opportunities for condom promotion.

Private sector

- Nongovernmental organizations (NGOs) are another resource in community condom promotion efforts.
- Condom social marketing (CSM) programs combine greater condom accessibility with affordable prices.
- Despite competition between the public and private sectors, it is essential that they work together if condom promotion efforts are to be expanded.
- Due to their influence, traditional healers should be relied upon for spreading positive messages about condom use.

CONDOM DISTRIBUTION AND LOGISTICS MANAGEMENT

Estimating condom requirements is essential to ensure that the supply of condoms keep up with an expanding demand. Clinicians should be vigilant in guarding against the use of condoms that have expired.

Adequate condom storage means protection from excessive heat or cold, ultraviolet light, moisture, rodents and pesticides. Failure to provide proper storage can make condoms unreliable.

EVALUATION OF CONDOM PROGRAMS AT HEALTH FACILITIES

All the components of a condom distribution and promotion program should be assessed periodically to maintain the program's effectiveness. Evaluation indicators are used for this purpose.

CONCLUSION

Although the development of microbicides and other barrier methods holds promise, the male latex condom remains the barrier method of choice in preventing STDs and HIV. Therefore, it is critical that STD program managers promote the condom as one of the most important tools for reducing STD and HIV infection.

INTRODUCTION

Prevention is the most important and effective strategy for reducing or controlling the spread of sexually acquired infections, including HIV. There are two main approaches to reducing the spread of STD/HIV: (1) avoidance of exposure, and (2) prompt and effective treatment for bacterial STDs.

Other chapters address STD diagnosis and treatment. Exposure to STDs and HIV may be avoided or minimized by:

- Eliminating the risk of exposure through abstinence, nonpenetrative sexual intercourse, or sex with one mutually faithful, uninfected partner
- Reducing the risk of exposure through avoidance of high-risk sexual partners, reduction in the number of sexual partners, and consistent and correct use of barrier contraception, particularly the male latex condom

Proper and consistent use of the male latex condom reduces the risk of STD.[1] For a man, a male latex condom reduces the risk of infection through penile exposure to cervical, vaginal, vulvar or rectal secretions, or lesions; for a woman, condoms prevent exposure of the female genital and rectal mucosa to urethral discharge, semen and penile lesions.

Individuals who have STDs are prime candidates for HIV, yet the opportunity to reach those who seek treatment for STDs is often missed. Although the male latex condom is an important method for preventing STD/HIV, it has been poorly promoted by STD program managers and is not readily available through STD services in many developing countries. A comprehensive STD service should include both biomedical and behavioral components that ensure both appropriate diagnosis and treatment, as well as appropriate patient education.

Critical messages for STD case management are often referred to as the "four Cs": counseling/education, condom promotion, compliance with antibiotic treatment and contact referral/partner notification for the treatment of sex partners.[2] Given the resource constraints common to public health services around the world, building strong services requires STD program managers to adopt a "fifth C"—connections to community resources. There is an urgent need to integrate critical messages—including condom promotion and distribution—across the spectrum of possible STD service delivery systems. These systems span public sector services (such as specialized STD clinics, primary health care centers, and secondary and tertiary health services) to private sector services (including pharmacies and chemist shops, private medical clinics, NGO community-based condom distribution and condom social marketing projects, and other community influencers such as traditional healers). To be most effective, STD program managers must be able to connect to all of these community resources to create a partnership for STD prevention promotion.

This chapter will focus primarily on the role of male latex condoms in STD/HIV prevention and how STD program managers can improve their promotion and distribution. It will cover the following issues:

- Efficacy and effectiveness of the male latex condom.
- Improving condom promotion, access, and connection to community resources.
- Condom logistics management.
- Evaluation and monitoring of condom programs at health facilities.
- Efficacy and role of other barrier contraceptives in STD/HIV prevention, including spermicides, female condoms, male plastic condoms, vaginal sponges, and diaphragms.

EFFICACY AND EFFECTIVENESS OF THE MALE LATEX CONDOM

Laboratory Data

Several laboratory, or in vitro, studies of condoms indicate that sperm and disease-causing organisms do not pass through latex condoms.[3,4] Male latex condoms have been shown in laboratory tests to be efficacious against herpes simplex virus, *Chlamydia trachomatis,* cytomegalovirus and HIV.[5-11] Although comparatively small numbers of latex condoms have been tested and studies are not definitive—for example, leakage in laboratory tests does not necessarily mean leakage during use—study results consistently show that high-quality latex condoms prevent the passage of disease organisms, including HIV.[4]

Human Data

Epidemiologic studies in human populations, or in vivo studies, indicate that STDs enhance HIV transmission.[12-16] When male latex condoms are used correctly and consistently, they are effective in substantially reducing the risk of contracting STD/HIV.[4,17-21]

Studies of serodiscordant couples—one infected partner, one not—offer the most compelling data, because regular exposure to an infected partner can be followed. In one multi-country European study, researchers followed 304 HIV serodiscordant couples for an average of 20 months.[17] Of these, 245 couples who continued to have vaginal or anal intercourse for more than three months after beginning the study and who answered questions about condom use were included in the analysis. The results revealed that none of the 124 seronegative partners who used condoms with each act of intercourse over two years became infected with HIV. Among the 121 seronegative partners using condoms inconsistently, 12 became infected.

In a second multi-center study, 343 HIV-positive Italian men and their HIV-negative female partners were followed for a median of 24 months.[18] Among the 305 women continuing to have vaginal intercourse with their HIV-infected partner, two percent of women who always used condoms became infected with HIV, compared to 15 percent of women who used them inconsistently or never. These two studies clearly show that consistent use of condoms decreases the risk of HIV infection. Moreover, inconsistent use carries significant risks of HIV infection.[4]

Studies such as those described above, which are designed to measure incidence of specific STDs and HIV, are expensive, time-consuming and impractical. A more practical measure of the impact of condom use in a health care facility may be the proportion of recurring cases of urethritis among men seen at the facility (Indicator V; see "Evaluation of Condom Programs at

Health Facilities" section). For example, as shown in Figure 1, promotion of condom use among military recruits in Rwanda led to a reduction in the incidence of urethritis from 12 percent to less than five percent over 16 months.[22]

Other Factors Influencing Effectiveness

While condoms are the most reliable technology currently available for preventing STD/HIV, their effectiveness can be compromised by improper use or product failure. Some product failures, such as condom breaks, may be caused by deterioration as a result of poor storage conditions (such as excessive exposure to heat or humidity) or poor manufacturing quality.[3,23] Other evidence indicates that individual behavior, not the condoms, is usually responsible for condom breaks and semen seepage. User-related failures are caused by incorrect and inconsistent use, including the following:[3]

- Failure to use a condom for each act of sexual intercourse
- Failure to put a condom on before any genital contact occurs
- Unrolling the condom before putting it on
- Slippage of condom resulting in spillage of semen
- Use of oil-based lubricant (e.g., cooking oils or lotion)
- Insufficient vaginal lubrication
- Re-use of the same condom for multiple acts of intercourse

In addition, to ensure that condoms are effective in preventing STD/HIV, high-quality condoms must be used consistently and correctly. In summary, condom users' attitudes and behaviors are as important to condom effectiveness as the quality of the condom itself.

Improving Condom Promotion and Access

Condom and STD Case Management

Condom promotion as part of STD patient counseling has been demonstrated to be an effective means of reducing high-risk behaviors and incidence of STD in both individuals and couples.[24,25] Therefore, condom promotion is becoming recognized as a critical component of effective STD case management.[26-29] For example, "advice on condom use" is one of the two variables (the other is partner notification) that WHO and AIDSCAP use to define "appropriate STD case management" for the core evaluation indicators for HIV prevention programs.

Condom promotion to STD patients should include (1) advice about using condoms, (2) a demonstration of correct use, and (3) provision of condoms to the patient. This chapter defines condom promotion broadly as a three-pronged effort consisting of the following:

Condom education and counseling: providing basic information about condoms (their effectiveness in preventing HIV or other STDs, the benefits of their use and where they can be obtained) as well as conducting a dialogue with each client to identify and address potential barriers to condom use.

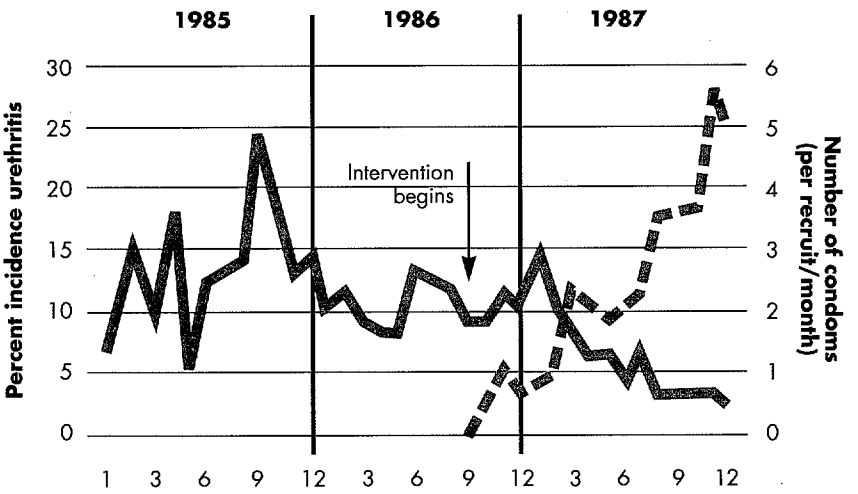
Condom skill building: using condoms and penis models to demonstrate correct use, and teaching partner negotiation skills for condom use.

Condom distribution: immediate dispensing of condoms and referring clients to sources for additional supplies.

These three components work together to support necessary preconditions to condom use, including increased personal knowledge, appropriate personal risk assessment, and self-efficacy with and accessibility to the required technology or tools. All three are necessary if behavior change is to be sustained over time.

Unfortunately, comprehensive condom promotion—counseling and education, skill building, and distribution—is seldom incorporated into STD case management. Field trials by WHO and AIDSCAP

Figure 1
IMPACT OF CONDOM DISTRIBUTION ON INCIDENCE OF URETHRITIS IN MILITARY RECRUITS IN RWANDA



testing the evaluation indicators for STD management showed that when this rigorous definition of condom promotion was used, comprehensive case management rarely occurred.[29] In Ethiopia, for example, the field trial observations of STD case management practices showed that 25 percent of practitioners mentioned condom use as an STD prevention tool, but only 15 percent provided advice on condoms **and** demonstrated correct use to their clients.[30] Only 10 percent of all practitioners in the survey mentioned condoms as a preventive measure, demonstrated correct condom use and provided their client with one or more condoms.

A 1993 survey of clinicians at STD clinics in Nairobi and Nakuru, Kenya, found that less than half the clinicians thought "adequate counseling" included providing condom advice, and less than 5 percent thought that demonstrating correct condom use was important.[31] But demonstrating condom use is important not only because it builds skills, but also because it breaks down inhibitions of individuals who may not have handled condoms in the past.

Arguments for intensifying clinic efforts to strengthen condom education, condom use demonstrations and condom distribution as part of STD clinical management include the following points:

1. A number of accepted behavior change theories suggest that accurate perception of one's need to change and self-efficacy in the skills necessary for change are essential to the adoption of new behaviors. Seeking treatment for an STD provides an important opportunity for an STD patient to accurately assess his or her personal risk of HIV or other STDs and to learn needed skills.[32-36]

2. Case management implies not only treatment but prevention. Information that will empower clients with the means of avoiding reinfection is as important as information to ensure treatment compliance.

3. Correctly used, condoms are a cost-effective intervention for reducing the spread of STDs because they are generally more available and are far less expensive than antibiotics.

4. Including condom promotion (and other risk-reduction advice) as part of case management increases the cost-effectiveness of STD services.

5. For many males in developing countries, STD clinic services may be the only contact they have with the formal health care system. Thus, a visit to a health clinic for STD services may represent one of the few opportunities for face-to-face condom education and skill building, both of which are critical for reducing the likelihood of reinfection.

CONSTRAINTS AND OPPORTUNITIES

The constraints to consistent and correct condom use are well-known. They include the poor image of condoms, their perceived unreliability, unfamiliarity with the product that leads to embarrassment, implied lack of trust in a partner if condom use is suggested, reduced sexual pleasure, inaccessibility and inconvenience.[9,37-43]

Health services also face constraints in attempting to provide comprehensive STD case management to clients. Some of these constraints include inadequate staff training, lack of time to spend with each patient, inadequate resources, staff shortages, lack of privacy and space, poor attitudes of staff and an overemphasis on the treatment aspects of STD management at the expense of prevention and behavior change.

Fortunately, these constraints—whether personal or institutional—can be addressed and minimized through careful examination and effective program planning *(see Chapter 2)*. The constraints are often synergistic, which means that the resolution can often be synergistic as well. For example, creating positive attitudes in clinic staff about condom promotion can help anxious and fearful clients open up about their lack of condom knowledge and use.

Table 1:
Ways to Improve Condom Promotion in Clinic-based Services

1. Develop a "Critical Condom Promotion Messages" list of four or five messages that clinicians can deliver to STD patients. These messages should be relevant to your particular community, addressing specific situations faced by your clients and referencing specific community outreach services.

2. Explore the possibility of using auxiliary staff to complement and reinforce clinicians' "critical messages."

3. Develop guidelines for conducting client risk assessments and counseling checklists for use by clinic counseling/condom promotion staff.

4. Solicit the support of staff from local nongovernental organizations (NGOs) and community-based organizations (CBOs) who could be trained to provide condom education and counseling both in the clinic and in the community.

5. Develop a condom promotion service delivery strategy, a work plan and training program for service deliverers.

6. Identify or develop small media—videos, audiocassettes, posters and pamphlets for people with low literacy—that promote condom use and address condom use constraints. Use materials in waiting rooms and in individual and small-group counseling settings.

7. Work with a condom social marketing program, if one exists in the country, to promote and sell a branded consumer product at or near service delivery sites.

CONDOM PROMOTION

STD program managers are often reminded of the original "four Cs" regarding critical messages for effective case management: counseling and education, compliance with antibiotic treatment, contact referral/partner notification for the treatment of sex partners and condom promotion.[2]

A number of communication strategies and tools can be used to promote condom use *(see Chapters 4 and 10).* Strategies range from one-on-one interpersonal counseling to small group discussions to large group "condom events"—dramas, rallies and community events. Facilitators of these strategies can also vary, from clinical officers or nurses to auxiliary health professionals to trained peer educators and community mobilizers and influencers.

A variety of tools also are available to support communication strategies. These include posters, brochures and booklets (so-called "small media") and community-developed AIDS dramas, radio shows, films and videos ("mass media"). Special tools include risk-assessment score cards, which help individuals assess their level of risk to HIV or other STDs; penis models, which help in condom demonstrations; and condom promotional items such as key chains, T-shirts, and bags, which help spread the message.

The broader the mix of communication strategies and tools, the more opportunities there will be to encourage condom use for STD prevention. Fortunately, STD program managers do not have to create all the components of this broad mix of strategies and tools for their service. By remembering the proposed "fifth C"—connection with community resources—STD program managers can ensure a lively, comprehensive condom promotion strategy.

Thus, it is important for STD program managers not to think of themselves as the sole or major providers of condom promotion for STD patients but instead to act as "condom promotion managers." In this role, STD program managers will be responsible for providing basic condom promotion messages and condoms directly to their clients while drawing upon the participation of the entire clinic health team as well as numerous external resources to ensure comprehensive case management. *(Table 1 summarizes strategies that can be used to improve condom promotion in clinic-based services.)*

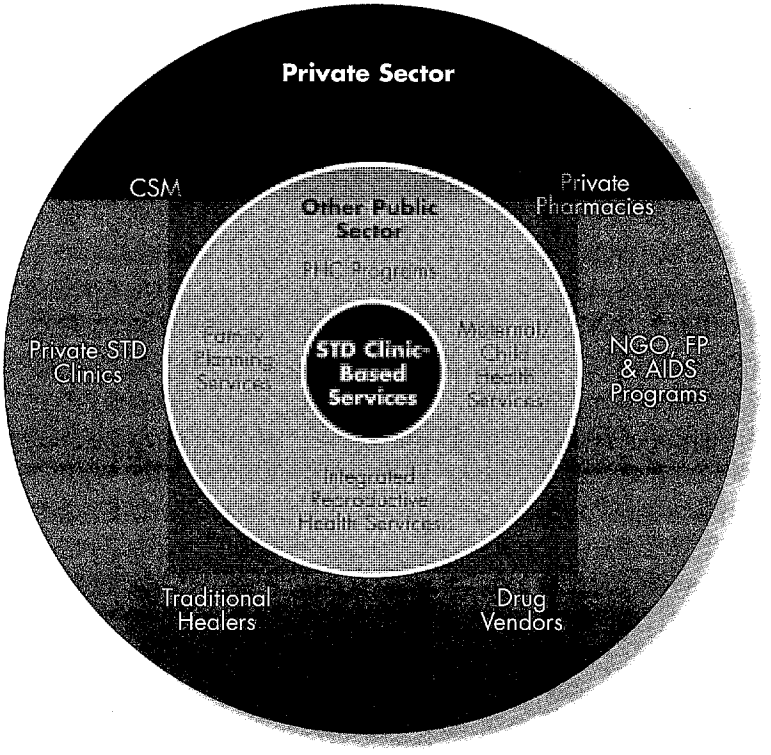
As STD program managers adopt the role of "condom promotion managers," they will need to explore diverse communication strategies (such as those noted above and elsewhere in this handbook) and local condom distribution access points, develop extensive community linkages and broaden the definition of what it means to be a service provider. STD service options are available through both the public and private sectors.

In the public sector, condom promotion for STD prevention must be available not only in specialized STD clinics but also widely through the primary health care system, including maternal and child health and family planning clinics. In the private sector, STD program managers need to connect with condom social marketing (CSM) projects, private STD clinics, pharmacies and chemist shops, and other community-based condom distribution programs, including those in the informal sector such as traditional healers. Each of these services can provide health education and condom promotion to extend the reach of effective STD case management. The STD program manager should

see himself/herself as the center of this system, connecting the various services available in the community *(see Figure 2)*.

The following section explores the role of the public sector in STD case management.

Figure 2
CONNECTING TO COMMUNITY RESOURCES



Effective case management requires STD program managers to become condom promotion managers looking outward from their client-based STD services to other public health services and to private sector services in the community.

PUBLIC SECTOR

Clinic-based STD services

Services within a clinic can be expanded by ensuring that all available health center staff are involved as much as possible in condom promotion and distribution. Nursing staff should be trained in providing one-on-one or small-group condom counseling and interpersonal communication. Other medical staff (medical assistants, nursing aides) as well as auxiliary and para-health staff (community volunteers, drivers, cleaners) can be trained to serve as condom demonstrators and promoters to individuals in small-group settings or in clinic waiting rooms. Videos shown in waiting rooms also have been used effectively to promote condom use both in developing and developed countries around the world.[44]

On the Caribbean island of St. Lucia, for example, nurses were trained to conduct risk assessments with patients waiting to see STD clinical officers and to counsel patients following treatment. Groundskeepers at a rural hospital in Chilema, Malawi, have been trained to demonstrate condom use in waiting rooms and to serve as peer educators to men who come to the clinic for STD services.

Health clinics already facing staff shortages may not have enough excess staff time to meet condom promotion needs. In that case, recruiting volunteer staff from local nongovernmental or community-based organizations, such as family planning associations, is an alternative strategy, particularly for clinics experiencing high demand for STD services. On-site assistance from such community groups, even once or twice a week, could also create a strong basis for community support for specific services.

Support from condom social marketing (CSM) projects through part-time detailing of CSM sales staff as condom promoters at busy clinics could be benefi-

cial to both the STD service and the CSM program. Providing free samples of the CSM product as part of the condom promotion presentation could benefit both the clinic and the CSM program.

Often clinic or volunteer staff are unfamiliar with condoms. Some may allow personal or religious biases to interfere with their ability to provide informative, nonjudgmental services to special client populations, such as youth or sex workers. Effective use of para-health and NGO volunteer "counselors" may require an initial commitment of time and resources to help these individuals confront their personal beliefs and attitudes about their potential clients, as well as provide training in technical information and counseling skills.

As a condom promotion "manager," a clinician should also examine his or her health facility's practices to ensure that they are "condom-friendly" for STD clients. The checklist below will help clinic managers assess how "condom-friendly" their site is.

Condom Accessibility to Clients

Are condoms easily accessible for clients? Condoms should be located where clients have access to condoms with minimal constraints. Unfortunately, this is not always the case. In Papua, New Guinea, for example, condoms are provided only to married STD patients. In other countries, youth seeking condoms may receive morality lectures instead—or two to three condoms at most. Many primary health clinics require men to register as clinic patients before they can obtain condoms, adding a significant time constraint and a disincentive to men. This practice runs counter to evidence that suggests that condom use increases when accessibility is enhanced.[45]

Educational Materials

Are condom educational materials and information provided to each STD patient? Are they available in the waiting room? Condom education can and should use multiple, reinforcing media, including small media (posters, brochures, video), interpersonal/small-group communication and innovative approaches (drama, local popular music, even games and rallies). Educational approaches should be adapted to the local situation, the resources available and the needs of the target audience.

Linking Prevention to Treatment

Does the clinic use every opportunity to link prevention and treatment? Educational materials, counseling messages and patient drug use instructions should always ensure that prevention messages are linked with treatment. In Zimbabwe, where STD case management has been integrated into the comprehensive primary health care system, clinicians promote this linkage by including a supply of condoms along with the antibiotics on the prescriptions they write.[45] The use of prepackaged STD therapy that includes antibiotics, condoms, education materials and referral cards provides a strong linkage between treatment and prevention.

Counseling

Does the clinic have private space where STD patients—particularly repeat clients—can be counseled by health educators, nurses or medical assistants and taught correct condom use skills? Are counselors trained in procedures for risk assessment, identifying/resolving condom use barriers and demonstrating correct condom use?

Clinic Supply

Does the clinic "send the right message" to STD patients about the importance of condoms by keeping an adequate supply on hand at all times? Are condoms properly stored to maintain quality? (See storage issues later in this chapter.)

Sources of Condoms in the Community

Are all clinic staff made aware of other sources of free and subsidized condoms in the community? Are they prepared to advise clients of these sources?

STD service providers need to be knowledgeable about and supportive of non-clinic-based condom distribution efforts for the following reasons:

- Some STD patients may prefer to obtain condoms from non-clinic settings.
- Condoms may need to be sought by potential users outside of clinic hours.
- Increasing reliance on private sector (including subsidized private sector) condoms will reduce the demand and the cost to the public sector for condom supplies.
- Community-based distribution and social marketing programs are more effective in providing condoms when and where they are needed.

Clincians who have created a condom-friendly environment can use their position of authority to reinforce critical condom promotion messages delivered by other clinic staff. This may be especially important in countries where age and personal status significantly affect the credibility of the messenger.[30,46] Such messages can be delivered during the standard five minutes to which clinicians are often limited for each patient.[46,47]

Critical condom promotion messages should:

- Reinforce the efficacy of correct use of condoms to prevent STD/HIV infection
- Direct the patient to follow up on communication counseling services available at the clinic or in the community
- Inform patients of two or three local sources for free or price-subsidized condoms
- Ensure that patients leave the clinic with an initial supply of condoms

Family Planning and Maternal/Child Health Services

Once clinicians have done all they can to improve condom promotion within their clinic setting, they should build linkages to related health programs and services, such as maternal/child health (MCH) programs and governmental and nongovernmental family planning (FP) programs. Such linkages can also extend the reach of a clinic-based STD program and serve as reinforcing communication channels and referral points.

MCH and FP programs are often the most developed health services available at primary health clinics. They are excellent venues for reaching women who are sexually active and who may have asymptomatic STDs, particularly where routine syphilis screening of antenatal women is conducted.[48] These programs can also educate women about (1) the importance of encouraging their partners with STDs to seek treatment, (2) the dangers of untreated STDs (particularly the risk of HIV and infertility), and (3) STD prevention, including correct condom use. STD program managers should seek to ensure that family-planning providers make condoms available to women at risk for HIV or other STDs even if they use another contraceptive for family planning.

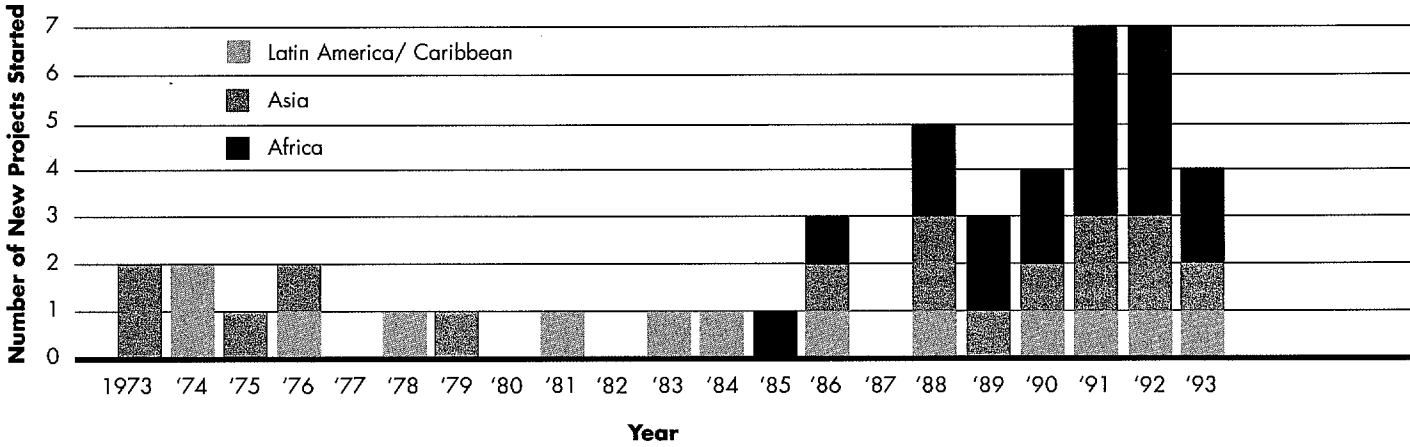
CONNECTING TO PRIVATE SECTOR SERVICES

Community-based NGO programs

Developing linkages to NGO-managed community-based distribution of condoms, condom social marketing, and HIV peer health education programs can expand the condom promotion efforts as well as clinical reach of STD services. In Zimbabwe, for example, community-based distributors of family-planning products have not only been trained to promote correct condom use, but also to teach clients to recognize STD symptoms and seek treatment. In Botswana, family welfare educators are providing similar support to clients of their community-based services.[46]

NGO-managed peer education programs for target audiences, including high-risk individuals, in communities, workplaces and bars have proven effective in

Figure 3
Trends in New Starts of Condom Social Marketing Projects



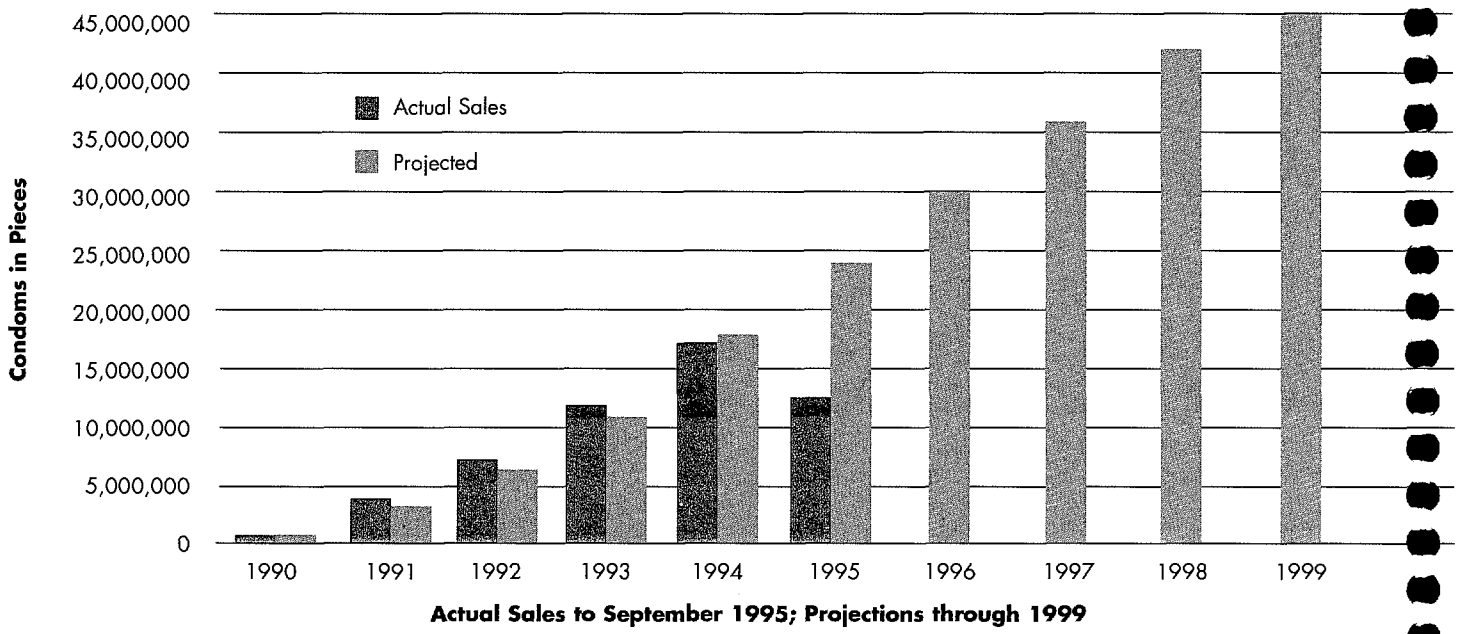
Source: PSI 1994 Condom Social Marketing Statisics

increasing condom use and other appropriate health-seeking behavior.[48-50] Closer and more formal linkages between STD service providers and peer educators can provide mutual support and synergistic strengthening of both programs. In the Dominican Republic, collaboration between the public sector health services and a peer education program for sex workers resulted in a decrease in syphilis prevalence among sex workers from 11.6 to 8.2 percent.[51] Such collaboration can include sharing behavior change communication materials, upgrading staff skills in condom counseling and health education, providing referral for condoms, and improving patient and partner follow-up.

Condom social marketing

Condom social marketing (CSM) programs combine vastly expanded condom accessibility with consumer-friendly promotion. Condom social marketing was first launched over 20 years ago; the first countries to test the concept were India, Colombia, Jamaica and Sri Lanka. These early programs proved the hypothesis that individuals would be willing to pay an affordable price for contraceptives in exchange for greater accessibility to the product. Interest in social marketing has grown rapidly over the last 20 years. Figure 3 shows the regional dispersion of the world's major CSM projects (defined as providing contraceptive protection to the equivalent of 10,000 people or more per year). The number of new CSM projects has doubled in the last five years. Most of the new projects started in the last ten years have been in Africa, which now has more projects than either the Asia or Latin America/ Caribbean regions. Programs around the world have demonstrated that making condoms available at an affordable price in places convenient to users can result

Figure 4
Ethiopia Social Marketing Program Condom Sales



Source: DKT Ethiopia

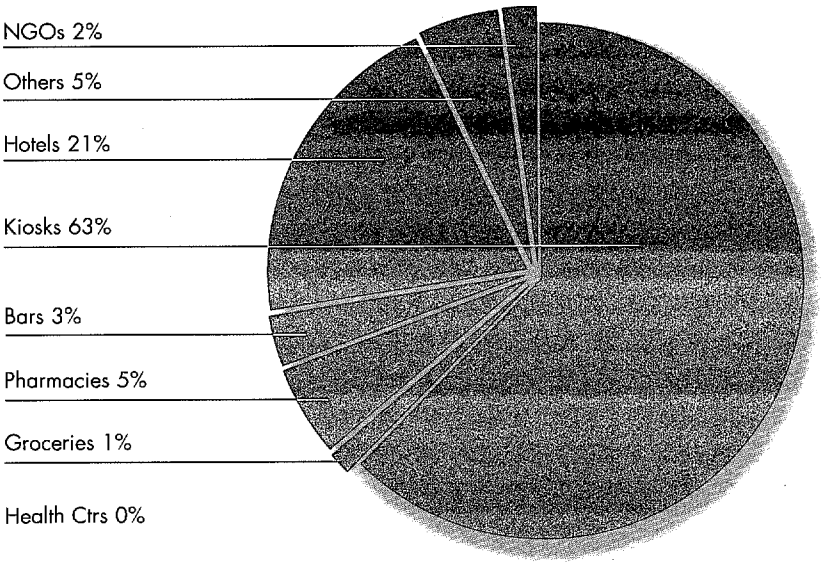
in staggering condom sales. As Figure 4 shows, rates of increase of sales of condoms are often impressive; condom sales in Ethiopia have grown from approximately 300,000 in 1990 to 11.8 million in 1993 and over 19.8 million in 1995.[52] Over a period of four years (1991-1995), AIDSCAP has provided 177 million condoms for HIV prevention, with CSM representing nearly 90% of the condoms provided. More than 5.6 billion condoms were sold through CSM programs worldwide in 1994.[52]

Condom social marketing programs sell brand-name condoms through a wide variety of sales points, including traditional chemist and small retail shops and a myriad of nontraditional outlets, such as bars, hotels, restaurants, market stalls, sidewalk vendors, brothels, kiosks, taxis and boat launches. Figure 5 shows the sales of condoms by outlet type in the Ethiopia Social Marketing Program. Over 90 percent of the condoms were sold through non-traditional outlets. In Cameroon, commercial sex workers have been trained to be condom salespersons in bars and brothels.[53] In Haiti, project managers have learned that NGOs can be effective distributors of CSM condoms and that the revenues help to sustain the often fragile NGO sector.[54] The use of NGOs as condom distributors in Haiti during the mid-1990s economic embargo resulted in sustaining condom availability when distribution through commercial outlets was severely compromised. In the Philippines, socially marketed condoms are being sold in bakeries, bookstores, barber/beauty shops and fast food outlets.[55] Social

marketing projects in countries around the world have found little difficulty in generating a high demand for condoms once barriers to accessibility have been reduced.

In addition to greatly expanding access to condoms through traditional and nontraditional sales outlets, CSM programs have demonstrated a unique ability to diminish social taboos surrounding condom use through their innovative use of both conventional and nonconventional advertising, comedy, street theater, promotional items and other techniques for changing attitudes. These strategies have served to reposition condoms in the minds of members of target audiences. As a result, the condom is no longer viewed as foreign, sterile medical technology, but rather as a simple consumer product that is easy to use, effective and increasingly popular.

Figure 5
ESMP 1994 Sales By Outlet Type

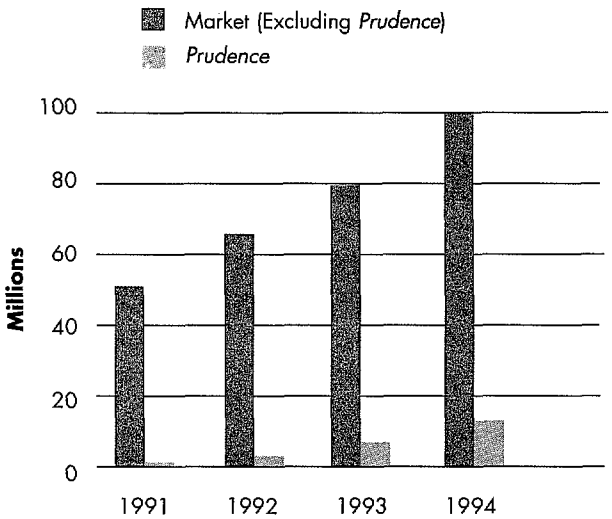


Condom social marketing programs begin from the premise, confirmed in Knowledge, Attitude, Behavior and Practice surveys (KABP surveys) in countries around the world, that most people know that using a condom correctly prevents HIV transmission. From there, CSM seeks to break down the major barriers to its use: embarrassment about discussing condoms, a lack of information about where to obtain them, and a lack of information about how to use them.

Many of the CSM-sponsored activities are fun and appeal to young people especially. For example, *Prudence* condoms are promoted across Africa through "condom soirées," rallies featuring music, games and dancing interspersed with both light-hearted and serious HIV education and condom promotion. In Burkina Faso, a youthful sales team holds dances and drama productions for its young target audience. In Benin, CSM sponsors a 10-day bicycle race and hosts a rally with music, games and condom demonstrations.[56] These activities, part of CSM's community-based education outreach, provide information about HIV, AIDS, other STDs and pregnancy prevention in a format that is understandable, entertaining and targeted to the attending audience.

Condom social marketing programs also use more traditional promotional strategies, including a liberal sampling of condoms; the distribution of promotional items, such as posters, T-shirts, pocket calendars, key chains and pens; and mass-media advertising where possible. The radio script in Box 1 was developed for *Maximum* condoms sold in Zambia. The script is part of a successful campaign that has resulted in increased sales. December 1992 product sales for Maximum were 435,000, but sales averaged 600,000 per month in the last six months of 1995.[58]

Figure 6
Brazilian Condom Market



One of the important benefits of CSM programs is their ability to impact condom sales and distribution generally. As Figure 6 shows, innovative advertising and marketing in Brazil caused the sales of the CSM brand, *Prudence,* to increase from just over 100,000 condoms in 1991 to approximately 1.2 million condoms three years later. During that same time, however, commercial sales of condoms, which had been stagnant in Brazil for years, doubled from 50 to 100 million.[57]

STD clinicians who are effective condom promotion managers can establish linkages with CSM programs by:

- Encouraging STD prevention as one of the standard CSM condom promotion messages in addition to prevention of unwanted pregnancy or HIV infection
- Providing basic training to socially marketed condom promoters to make them more effective communicators about treatment and prevention of STDs, and to offer individuals a place where they can obtain quality services
- Seeking the part-time assistance of CSM promoters in giving condom presentations and demonstrations at the clinic and in providing sample condoms for distribution by clinic staff

Condom social marketing programs are also beginning to explore more direct linkages to STD treatment and prevention. Chapter 13 describes in detail an innovative strategy to sell prepackaged therapy and prevention (antibiotics, condoms, and partner referral cards) kits for treatment of urethritis.

Private sector health services

Coordination with private sector STD services may be difficult for public sector clinic managers, because the former is independent and there is some competition between the two sectors; however, coordination is important for the following reasons:

- Private sector services are often the first (and sometimes the only) places where men seek treatment for STDs.[58,59]
- The private sector often reaches a greater proportion of high risk groups than the public sector has the resources to do.
- Private practice may be more heavily focused on treatment than prevention.
- Physicians and pharmacists may be unaware of research results on changing etiologies or the reduced efficacy of drugs due to resistance.
- Pharmacists/chemists faced with clients who cannot afford a full course of therapy may dispense an incomplete regimen, thereby contributing to drug resistance.
- Private sector physicians and pharmacists may not promote condom use.

Research studies of STD knowledge, beliefs and treatment-seeking behavior in Ethiopia and Senegal report that individuals with STDs frequently seek

Box 1

Radio Spot for *Maximum* Condoms

David: Jane, there is something I need to discuss with you. Mary told me that she saw you buying condoms in the shop yesterday. Is this true?

Jane: Yes, David, it is true. This colleague of ours...(laughs) there is no such thing as a secret. I bought a packet of MAXIMUM condoms. They are for us.

David: What an insult! You think I'm the sort of person who can give you AIDS?

Jane: That's not what I think, David. You know that I love you. But either one of us could be infected and not know about it. I want to use condoms for your sake as well as mine.

David: But Jane, you and I have been together for awhile now.

Jane: That's true, and I'm glad that we're together. But I've heard that people can carry the AIDS virus more than 10 years without showing any sign. So why take chances? Let's be sure by using MAXIMUM condoms.

Voice over: Jane is being sensible. She has learned that condoms prevent the spread of sexually transmitted diseases such as AIDS. David is surprised, but he is mature and knows that Jane is right. Using a condom can help both Jane and David take control of their lives by avoiding AIDS and unwanted pregnancies.

ANNOUNCER: This message is brought to you in the public interest by MAXIMUM condoms.

MAXIMUM Condoms.
Strong for Maximum Protection.
Sensitive for Maximum Pleasure.

treatment from pharmacists, traditional healers, and/or street vendors before going to a public clinic.[60,61] These sources can be and often are oulets of condoms.

Public health clinicians can help improve and link private and public STD services by:

- Conducting continuing education courses for physicians and pharmacists that focus on client communication and correct condom use skills for prevention
- Disseminating research results from etiologic and antibiotic sensitivity studies conducted through the public sector
- Sharing condom promotion and STD prevention materials with them
- Encouraging dialogue on patient referrals

Encouraging private sector pharmacists and physicians to promote condom use will create reinforcing communication channels for this important message. Pharmacist and medical practitioner associations in countries around the world, including Tanzania, Nigeria, Thailand, Nepal, Philippines, Brazil and Jamaica, have demonstrated an interest in specialized continuing education and training in condom promotion. Efforts to date to encourage participation of pharmacists and private phsicians in HIV/STD prevention, including condom promotion, have been very promising. In Nigeria, the training of pharmacists and pharmacy operators in HIV prevention and the introduction of socially marketed condoms at the pharmacy resulted in increased sensitization of these community health providers to HIV/AIDS issues, improved client counseling and education, and a higher level of condom distribution.[61] In India and Nepal, physicians along truck routes were trained in STD treatment and prevention as well as communication skills for working with truck drivers. Program managers preliminarily report improved, anonymous services and greater condom use.[62]

Traditional healers

Other potential condom educators and promoters include traditional healers. In South Africa and Uganda, healers have accepted and passed on HIV prevention counseling and correct condom use skills for prevention of HIV and other STDs.[63,64] Given the important role of traditional healers in providing health care in many developing countries, STD clinicians cannot afford to ignore their potential for reinforcing condom promotion messages and referring patients to health clinics.

CONDOM DISTRIBUTION AND LOGISTICS MANAGEMENT

In ideal situations, condom distribution is an integral component of STD case management—as is the distribution of appropriate antibiotics. As clinicians who favor single-dose antibiotics over long, multiple-dose regimens know, distributing drugs and condoms at the point of service delivery increases the likelihood that the commodity will be obtained and used.[45]

Most clinics will store some condoms for distribution to clients. Depending on the particular clinic and national condom distribution system in place, the source for a supply of condoms will be a district hospital, a regional medical store facility or central medical stores.

Estimating Condom Requirements

Clinics known to distribute condoms must maintain stock levels and quality assurance procedures to ensure that adequate supplies of high-quality condoms are available at all times. To do so requires careful condom supply forecasting and stock management.

Most countries have adopted sound condom supply management, storage and distribution systems at the central warehouse level. Many have also established reasonable condom management procedures and systems at the secondary, regional or middle levels. But clinics and other health facilities often lack appropriate ordering and management procedures and systems, resulting in stock outages or even distribution of condoms that have long passed their expiration date.

Since most condoms do not specifically state an expiration date, STD program managers need to know how to correlate the date of manufacture (which is often stamped on the condom or at least noted on the condom shipping carton) with an expiration date. A general rule of thumb states that condoms are safe to use within three years of manufacture *assuming* they are appropriately stored to prevent accelerated damage beyond their normal "life span."

Condom supplies are generally provided at fixed intervals, either monthly or quarterly. The length of this interval is often a function of ministry delivery schedules but will also depend on the storage capacity of the health facility. To make a condom supply system work, clinic supply managers must know:

- The average number of condoms used during the relevant interval
- The lead time required between placement and receipt of condom supply orders
- The number of condoms—so-called "safety" stock —required to meet unanticipated delays in delivery

Clinic supply managers also must know whether changes in any of the factors listed above can be anticipated during a specific period. Such changes might include the following:

- A newly instituted condom promotion program (such as those described earlier)
- Plans to aggressively promote STD health-seeking behavior among youth
- Establishment of a new, regional commodity warehouse system
- A planned reduction in delivery schedules due to fuel shortages

Once a clinic supply manager knows the average distribution figures, lead time and safety stock requirements, he or she can calculate the appropriate "maximum stock level" for a facility. Condom ordering is then simply a function of subtracting stock-on-hand from the maximum stock level.[65]

Condom Storage

The second element of effective supply management is ensuring that stocks are properly stored and issued. Proper storage is important because the quality of latex condoms deteriorates over time. Distributing condoms that have been improperly stored or are too old will increase the likelihood of product failure. Condom breakage exposes people to risks of pregnancy, STDs and HIV and can result in a decrease in confidence in the product.

Fortunately, correct condom storage procedures are simple to follow. They include protecting condoms from excessive heat or cold, ultraviolet light, moisture, rodents and pesticides.[66] (See Table 2, "Six Steps to Proper Condom Storage.")

Condoms arriving in cartons that have been crushed, punctured or that demonstrate evidence of water soaking or contact with chemicals should not be distributed. Condoms that are brittle or gummy or have broken wrapper seals should never be used. Condoms that are discolored may also be unreliable, but if the discoloration is limited to the packaging material, the condoms themselves are usable.

Even when condoms appear to be in acceptable condition, wise managers will be alert to feedback from users. Increased reports of breakage, particularly when users can demonstrate correct condom use or have not had breakage problems in the past, can signal poor quality, which may not be visible. In such instances, reports should be forwarded to the immediate distribution source, and efforts should be made to replace any remaining supplies with new stock. Since latex breaks down over time, it is important that the condoms with the earliest manufacturing date always be dispensed first.

Condoms should be given out as soon as possible. In no instance should programs dispense condoms that are five or more years old.[67,68] Such condoms should be returned to the central medical stores for appropriate and certain destruction to ensure that they do not get into the formal (or informal) distribution system.

Table 2

Six Steps to Proper Condom Storage

1. Provide adequate ventilation by storing cartons on pallets or otherwise off the floor for enhanced air circulation.

2. Prevent water damage by storing cartons off the floor and away from open windows and leaky roofs.

3. Control pests by keeping storage areas free of food or debris that might attract rodents or insects. Use pesticides very carefully, and do not store pesticides in the same storeroom as condom stock.

4. Prevent exposure to ultraviolet light, air pollution and chemical products, including petroleum and liquid solvents. (Sunlight, light from fluorescent lamps, sparks from electrical motors and lightning from electrical storms can create ozone that can damage condoms.) Store condoms in their shipping cartons as long as possible.

5. Promote safety by storing condoms in a secure, locked area with limited access. A fire extinguisher should be located nearby if possible.

6. Keep accurate records to ensure that stocks are used according to "first to expire, first out (FEFO)" rule.

EVALUATION OF CONDOM PROGRAMS AT HEALTH FACILITIES

Periodic assessments of the reach and impact of condom promotion and distribution efforts are essential if such efforts are to be fully integrated into the STD case management system. The following issues must be addressed as part of an assessment of the condom promotion and distribution program in a health care facility:

1. *How good is the logistics system for condoms at the facility?* The logistics system should consist of explicitly defined methods for adequate storage and effective distribution that ensure reliable and constant availability of high-quality condoms.

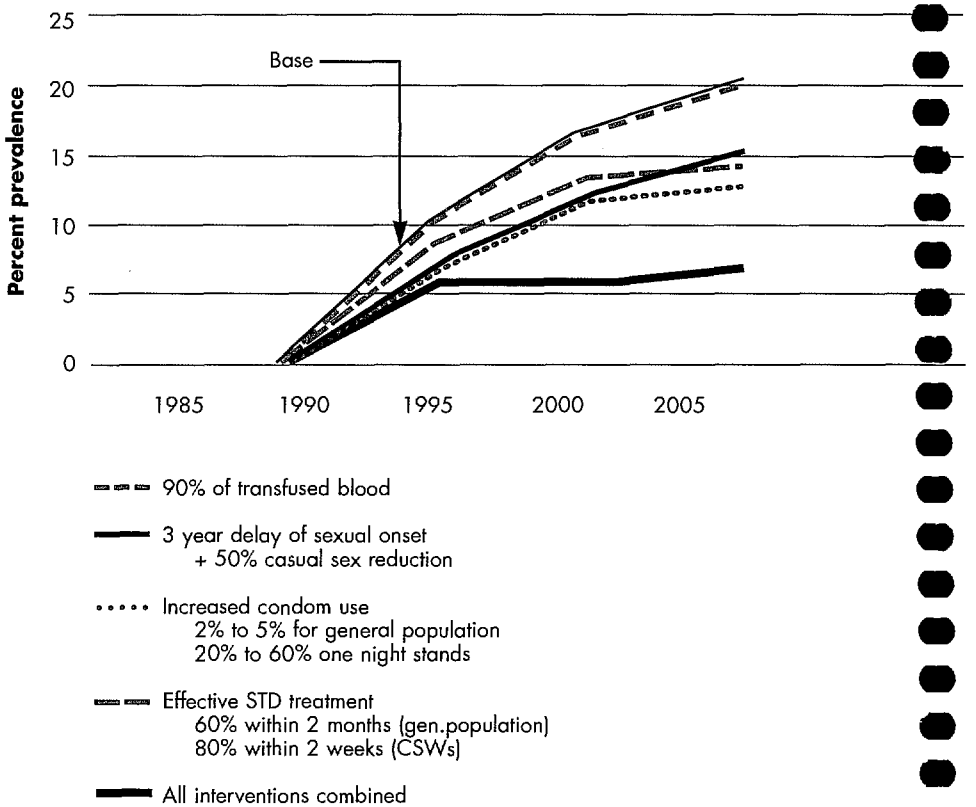
2. *How consistently are condoms promoted in the STD case management efforts of clinic staff?* Included in this assessment should be an examination of the extent to which community linkages have been established and the vibrancy of those linkages.

3. *How effective are the promotional and marketing services?* How successful is the program in improving acceptability, accessibility and use of condoms and distribution and/or sale of condoms to individuals seeking care at the health facility?

4. *How effective is the health care facility's condom program in preventing further spread of STD/HIV?* A measure of STD incidence or prevalence is the ideal indicator for assessing the impact on STD/HIV prevention. But are STD/HIV indicators sensitive enough to measure the full impact of condom use?

Figure 7

PROJECTED EFFECT OF AIDS INTERVENTIONS: MODELING OF AN AFRICAN CITY



Mathematical modeling of the AIDS epidemic suggests that condom use can lead to a measurable reduction in the prevalence of HIV. Figure 7 shows the projected impact of condom use on the prevalence of HIV in an urban African population.[69] This model suggests that if condom use rates increased from two to five percent among the general population and from 20 to 60 percent in casual sex encounters, then the prevalence of HIV could be reduced by as much as two-thirds over 15 years. As pointed out earlier in this chapter, increased condom distribution among Rwandan military recruits did correlate with significant reductions in the incidence of urethritis.[22]

Evaluation of STD case management is addressed in Chapter 14 of this handbook. Evaluating the condom promotion/distribution component should be an integral part of this assessment and should be planned in conjunction with assessing the broader service. The way to specifically evaluate the four major issues noted earlier is by examining the quality of services as well as the result of those services as measured in increased condom use and, ultimately, reduction in STD episodes.

Evaluation Indicators

Table 3 describes five indicators for evaluating condom programming. Indicator I measures the availability of condoms as a ratio of the total number of condoms available at the health facility for distribution as a function of the total number of individuals seeking STD care. Indicator II measures the results of condom promotion and marketing activities by showing the ratio of the number of condoms sold or dispensed per individual seeking STD care in the health facility during the preceding 12 months. This ratio, when compared to Indicator I, should provide a sense of the level of distribution given the availability of stocks.

Indicator III is a standard measure adopted by AIDSCAP, WHO and others to measure the quality and consistency of appropriate case management services as provided by clinic staff. It measures the percent

Table 3

Indicators for evaluating a condom program at a health facility

Activity	Indicator
Condom availability	**I.** Total number of condoms available at health facility for distribution during the preceding 12 months / Number of individuals presenting or seeking STD care in health facility during the preceding 12 months
Condom promotion/ marketing	**II.** Number of condoms distributed or sold at health facility during the preceding 12 months / Number of individuals presenting or seeking STD care in health facility
	III. Increase in reported condom usage of individuals presenting or seeking STD care in health facility
Condom effectiveness	**IV.** Number of individuals presenting with an STD or for STD care in health facilities who received advice on condoms and partner notification / Number of individuals presenting with an STD or for STD care
	V. Number of repeated episodes of urethritis in men presenting at health facility in preceding 12 months / Total number of episodes of urethritis in men in preceding 12 months

of persons who present with an STD or are treated for an STD who are provided with information on condom use and partner notification. Indicator IV, also a ratio, assesses the effect of the promotional and marketing activities on reported condom use rates of individuals seeking STD care at the health facility. Finally, Indicator V provides a measure of the effectiveness of the program by assessing whether increased promotion and reported use of condoms is, in fact, resulting in fewer repeat episodes of urethritis in men.

Data needed for Indicators I, II and V will be available from clinic records, particularly from the logistics management system and the clinic record book. Data for Indicator III can be collected through a standard KABP questionnaire of men in the community served by the clinic. The questionnaire can also ask men to report the number of urethritis episodes during the past six months as a way of measuring frequency of STD syndrome incidence. Indicator IV information can be collected in direct observation of the behaviors of clinic staff as they interact with clients. These data should be collected prior to efforts to strengthen the condom promotion component of STD case management and again 12 months later to measure change from the baseline.

Assessing how well staff are connected to other community activities also should be included in the evaluation of the program. This assessment can be accomplished through several means, including listening for community services referrals during the direct observations of case management (Indicator IV), conducting "exit" interviews with clients on a periodic basis to see whether the clinician or any other staff member provided information about other community sources of condoms, and keeping a clinic log of community linkage activities involving clinic staff. These activities might include staff participation in "condom soirées" sponsored by the CSM project and tracking the following items: the distribution of print materials that list condom sources in the community, the number of visits to the clinic by community-based HIV/AIDS programs to provide education and promotional activities at the clinic, and other outreach efforts.

FUTURE PROSPECTS: OTHER BARRIER CONTRACEPTIVES IN STD/HIV PREVENTION

At present, latex condoms are the most widely used barrier method for the prevention of HIV. Yet even in the face of effective condom promotion, some clients who need to use condoms will find it difficult to do so. Since condoms are a male-controlled technology and since women often have less power in sexual relationships, women are often put at risk for HIV or other STDs when their male partners refuse to use condoms. Teaching women condom negotiation strategies can help, but these skills can be insufficient when partners are intoxicated or otherwise unreasonable. Women require methods they can control themselves to protect themselves. How effective are other barrier contraceptives in preventing the spread of STD/HIV? Correct and consistent use of barrier contraceptives (including spermicides alone or in combination with other barrier methods such as the vaginal sponge and the diaphragm, the female condom and the male plastic condom) may provide some protection against STD/HIV.

SPERMICIDES, INCLUDING THE SPONGE, DIAPHRAGM AND CERVICAL CAP

Spermicides are chemical barriers that inactivate sperm and other organisms. They are sold and used in the form of a cream, gel, foam, suppository or film. A spermicide may also be used in combination with a physical barrier (such as a male or female condom, vaginal sponge, diaphragm or cervical cap). The spermicide agent in most products sold in the United States, Europe and Japan is nonoxynol-9 (N-9), benzalkonium chloride (BZK) and menfegol, respectively.

In vitro efficacy

Results from laboratory studies of N-9 spermicides show that N-9 effectively inactivates treponomes, gonococci, chlamydiae, herpes virus and organisms causing bacterial vaginosis.[70-72] Other laboratory studies confirm that BZK and menfegol exhibit similar efficacy against sperm and these STDs.[73-75] N-9 spermicides, as well as BZK and menfegol have also been shown in laboratory tests to inactivate HIV-4.[76-78]

In vivo effectiveness

Results from several epidemiologic studies support those laboratory studies mentioned above and consistently demonstrate that spermicides, used either alone or in combination with other barrier methods, reduce the incidence of gonorrhea, chlamydial infection, trichomoniasis and bacterial vaginosis.[4,21,79-82] However, the relationship between N-9 use and HIV incidence remains unclear and currently inconclusive.[21,83,84] Only two human studies have been published and their findings conflict. In one study, a group of Nairobi commercial sex workers regularly used a contraceptive sponge with N-9 and were compared to a control group.[85] HIV seroconversion rates after two years were 56 percent and 41 percent in the sponge and control groups, respectively. In assessing the results of this study, it is important to consider several limitations of the study, including the sponge's high dose of N-9 (one gram) and its tendency to dry in the vagina (which may lead to increased trauma and ulceration as a result of sexual intercourse).[21,86,87]

In the second study, which compared the use of a much lower dose of N-9 (100 mg) and incidence of HIV infection, 272 seronegative women in Cameroon were supplied male latex condoms and 100 mg N-9 suppositories and were asked to use both during each act of intercourse.[88] Although 19 HIV infections occurred, HIV incidence decreased as N-9 consistency increased.[89] In an unpublished study carried out in Zambia, those who used N-9 suppositories had a reduced risk of HIV infection.[83]

Use of N-9 with the vaginal sponge, diaphragm or cervical cap

Vaginal sponges are impregnated with a spermicide and inserted into the vagina before intercourse. Laboratory studies show that spermicides in the vaginal sponge have inactivated HIV, chlamydial and trichomonal infections.[1] In addition to the Nairobi study detailed above, two other observational trials of the contraceptive sponge showed 25 to 40 percent reductions in chlamydial infection, and 10 to 69 percent reductions in gonorrhea.[81,82]

Diaphragms and cervical caps should be used with spermicides and are inserted into the vagina to block the cervix during intercourse. Observational studies of these barriers used together with spermicides show a reduction in STDs of between 50 and 100 percent.[20]

It should be noted, however, that because diaphragms and cervical caps shield only the cervix and leave a portion of the vagina exposed, these barriers may offer better protection against organisms that infect the cervix (such as *C. trachomatis* and *N. gonorrhoeae*) than against other organisms that can be transmitted through the vagina or external genital contact (including HIV, herpes simplex virus, *T. pallidum* and *H. ducreyi*).

Genital irritation

Although N-9 spermicides used alone or in combination with other barrier methods may offer some protection against STDs/HIV, other studies have reported genital irritation following N-9 use.[83,87,90-92] Reported adverse reactions include discomfort with use, an increase in genital ulcers, genital itching and burning, and inflammation. Results from these studies indicate that the more frequent the use of spermicides and the higher the dosage, the more elevated the rates of genital irritation. When lower doses of spermicide are used, increased risk is minimal or not present.[4]

Table 4

Reported Advantages and Disadvantages of the Female Condom

Advantages
Female controlled
Insertion before intercourse (Less disruptive to sex)
No need for immediate withdrawal after ejaculation
Minimizes sperm spillage
Easy removal
Lower loss in sensitivity
Stronger and stores better than latex
May be used with oil-based lubricants
Disadvantages
Difficulty in use (insertion difficulty; may be pushed into the vagina)
Inconvenience of use (noisy and messy)
Too large
Discomfort/pain (caused by inner and outer rings)
Reduced pleasure
Penile misrouting (penetration outside device)
Inappropriate for some sexual positions
Relatively expensive

The Female Condom

The female condom is a soft, loose-fitting plastic pouch that lines the vagina and protects the cervix, vagina and external genitalia. The pouch has a soft, flexible ring at each end. The closed end of the female condom is inserted and anchored inside the vagina. The open ring remains outside the vagina after insertion, protecting the labia and the base of the penis during intercourse. It is prelubricated and is intended for one-time use. The female condom, sold as Femidom™ in Europe and Reality™ in the United States, is commercially available in Switzerland, Britain, Austria, Netherlands and the U.S.

The efficacy of the female condom in preventing STDs is inconclusive, although results from laboratory studies and a few epidemiological studies indicate that the female condom may offer some protection against pregnancy, some STDs and HIV.[93-98]

In vitro efficacy

Drew and co-authors used an artificial intercourse model to test the permeability of the female condom to cytomegalovirus and HIV.[97] Results from the three trials showed no viral leakage.

In vivo effectiveness

Limited epidemiologic research has been done on the effectiveness of the female condom. Results from a randomized trial of the female condom and diaphragm showed no significant trauma to the vagina, cervix or vulva of women using either devices.[99] In another study of 104 sexually active women, consistent use of the female condom protected against recurrent vaginal trichomoniasis.[97] Reinfection with *Trichomonas vaginalis* occurred in seven out of 50 (14 percent) of controls, in five of 34 (14.7 percent) non-compliant users, but in none of 20 compliant users.

Acceptability

Results of acceptability studies of the female condom in African, Asian, European and American women are mixed. [1,98-101] In a comparative study of

the male and female condom in Cameroonian sex workers, more than 90 percent of women reported that they liked the female condom and almost two thirds preferred the female condom to the male condom. Half of their clients reported that they liked the female condom; in fact, 40 percent preferred the female condom over the male condom. Breakage rates were 13 percent for the male condom and 9 percent for the female condom. Results of studies of married or cohabitating women in Kenya reveal that over three-fourths of the women liked the female condom better or about the same as the male condom.[98] However, in two acceptability studies among sex workers in Thailand results were less favorable.[101,102] Continuation rates in the two trials were zero and 43 percent, respectively.

Table 5

BARRIER CONTRACEPTION AND STD/HIV PREVENTION

MALE-CONTROLLED CONTRACEPTIVES

Method	Comments
Latex condom	Barrier method of choice for STD/HIV prevention. Effective if used consistently and correctly.
Plastic condom	Limited data. Expected to be as effective as male latex condoms in STD/HIV prevention.

FEMALE-CONTROLLED CONTRACEPTIVES

Method	Comments
Spermicides (N-9)	Reduces spread of most STDs. Some data on HIV prevention. May cause vaginal irritation in high doses and with repeated use.
Vaginal sponge*	Reduces spread of some STDs. Limited data on HIV prevention.
Cervical cap*	Reduces spread of some STDs. No data on HIV prevention.
Diaphragm*	Reduces spread of some STDs. Limited data on HIV prevention.
Female plastic condom	Limited data. If acceptable and affordable, expected to be as effective as male condoms in STD/HIV prevention.

** Used with N-9 spermicides.*

Advantages and disadvantages

Some of the reported advantages and disadvantages of the female condom are outlined in Table 4. The female condom has the advantage of offering women more control over their bodies than the male condom. However, the female condom's role in STD/HIV prevention will continue to be limited until its acceptability improves and issues involving reuse and its high price (U.S.$1.00-$4.50) are resolved.

THE PLASTIC MALE CONDOM

The escalation of the STD/HIV epidemics throughout the world and drawbacks to the male latex condom have encouraged the development of male plastic condoms.[1] These condoms are made to be thinner, stronger and more sensitive than male latex condoms. They are not as susceptible to poor storage conditions and can be used with any type of lubricant. No clinical efficacy data exist yet on the effectiveness of the male plastic condom for prevention of pregnancy and STDs.

Other Barrier Methods in Development

No data are available on the efficacy of either a diaphragm or a cervical cap used without spermicide in the prevention of STD/HIV. Moreover, despite promising data from several studies, consensus among health care professionals has not been reached on the roles of spermicides (used alone or in combination with barriers), the vaginal sponge and the female condom in preventing STD/HIV. Table 5 provides an overview of currently available barrier contraception, along with the benefits and constraints of each.

Although it will take years of development before new barrier methods become available, some new HIV microbicides are being studied, including sulfated polysaccharides (compounds that block infection of vaginal or cervical cells); temperature-sensitive gels that may disperse infection-fighting drugs in the female genital tract; and new formulations of spermicides.[102]

CONCLUSION

Promising new microbicides and other more recent barrier methods such as the female and plastic male condoms need to be adequately studied in order to expand options for STD/HIV prevention. Until then, the male latex condom remains the barrier method of choice in preventing STDs and HIV. Therefore, it is critical that STD program managers accept the condom as one of the most important tools for helping to reduce STD and HIV infection. It is also important that STD program managers establish linkages to all of the sources of condom promotion and distribution available in the community to ensure that maximum accessibility and use are achieved.

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CHAPTER 6

Training in STD Management

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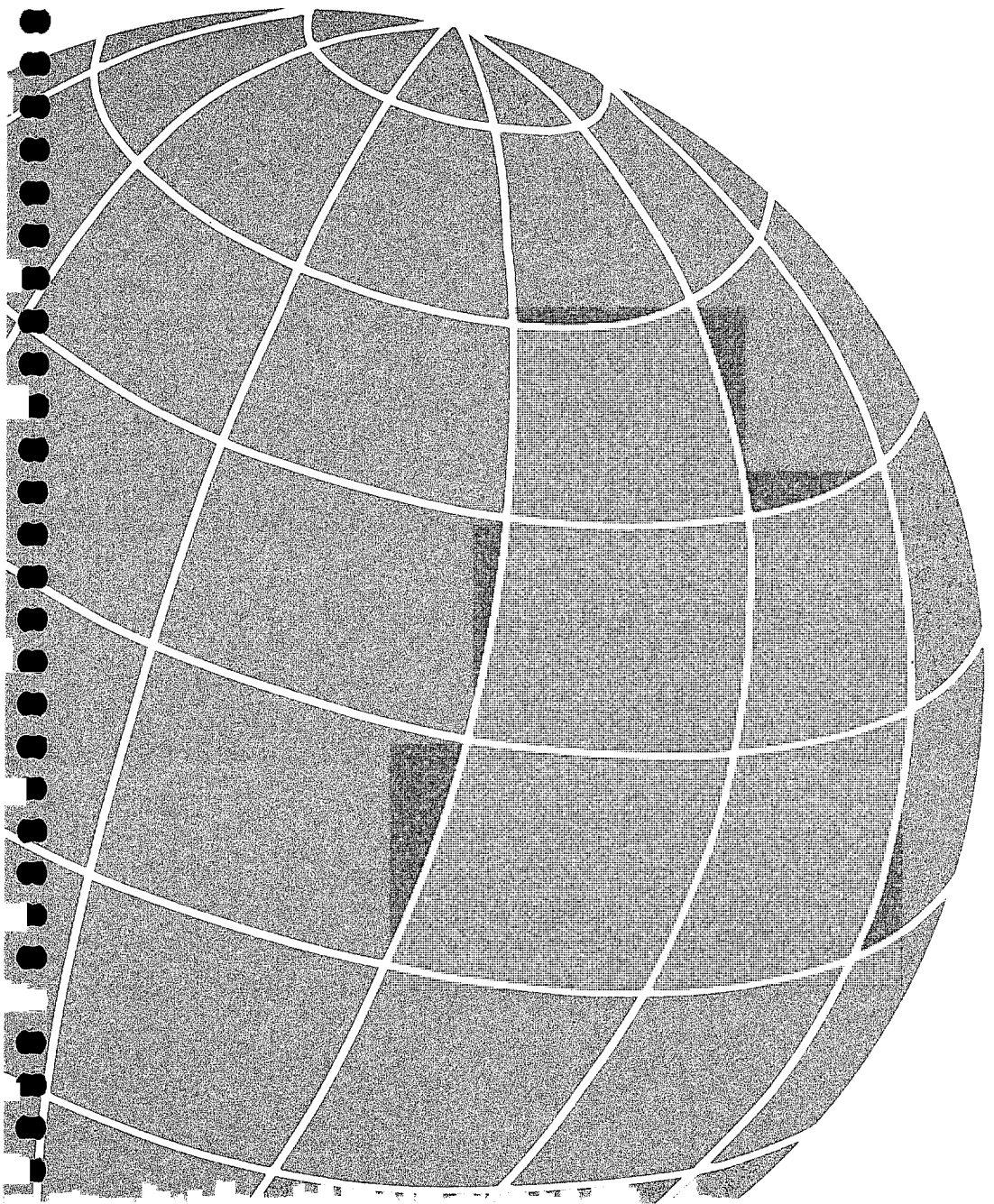


preview CHAPTER 6

Training in STD Management

INTRODUCTION

This chapter provides STD program managers with the information and tools they need to develop and sustain an STD training program for health care providers.

PLANNING HEALTH WORKER TRAINING

To develop a plan for health worker training, take the following steps:

- Conduct a training needs assessment.
- Set course objectives and criteria for course participants.
- Select methods and techniques.
- Design each training session.
- Determine course participants.
- Determine resources needed.
- Develop an evaluation plan.
- Prepare a training proposal.

TRAINING OBJECTIVES

Objectives should be behavioral and state what the learner should be able to do at the end of the course. Some examples:

- Participants using a flowchart will be able to diagnose and manage men with urethral discharge.
- Participants will be able to describe and demonstrate correct condom use.

SPECIFIC TOPICS IN THE MAJOR AREAS OF COURSE CONTENT

- STDs: transmission, control and the syndromic approach
- Clinical management of STDs using the syndromic approach
- Patient education for behavior change
- Partner management and reporting systems

RESOURCE NEEDS

Both the human and financial resources needed for a training session should be identified. Cooperating with other public or private sector groups is a way to expand resources.

Sample exercises are an important resource for trainers to use. An example is the AWARE Scorecard *(see Appendix 2),* which helps to raise awareness about STDs and AIDS.

THE EVALUATION PLAN

Managers should ensure that evaluation occurs in several different ways. Possible evaluation methods include the following:

- Knowledge pre- and post-tests
- Before-and-after attitude assessment
- Skill evaluation
- Participant feedback
- Trainer/facilitator evaluation

SUCCESSFUL TRAINING: KEY ISSUES

For training to have a long-term impact, it must have support that is sustaining. Some suggestions for helping to bolster training include:

- Arrange supportive supervision.
- Keep training short.
- Involve community groups.
- Stimulate continuing education.

TRAINING FOR THE PRIVATE SECTOR

Training also should be made available to private sector practitioners. However, sometimes they are difficult to access. Some possible approaches to this challenge include:

- Working with national medical associations
- Working with training centers to give recognition
- Providing mailings (e.g., newsletters and manuals)
- Writing key articles for regional or national journals

INTRODUCTION

STD managers play a critical role in supporting training programs that are well-designed and relevant to the needs of health-care workers, and this chapter discusses preparing them for this undertaking. Training providers is a critical component in promoting improved STD prevention and care. The chapter gives managers information about training resources, design tips and principles to guide their work with consultants or staff in designing training programs that result in improved STD case management.

Training health-care workers in STD case management is an ongoing process as more is learned about infections, effective prevention methods and better treatment techniques. Consequently, learning is a life-long commitment that needs continuing follow-up and supervision by managers, and openness and enthusiasm for new methods and materials by practitioners.

As more partnerships develop in future between the public and private sectors for STD prevention and control, sharing successful training methods and components will become more important to keep up with the challenge of training more trainers with potentially fewer resources.

STD TRAINING CONCEPTS

The Focus: Syndromic Management

The syndromic approach to STD management—early, effective diagnosis and treatment of STDs *(described in greater detail in Chapter 8)*—is designed to reach more people than are currently being treated using standard etiologic or clinical diagnosis. Syndromic management is based on the signs and symptoms with which a client presents and requires no laboratory support. A health-care provider is guided by a flowchart to the most effective treatment for a given set of signs and symptoms. With this simple technology and adequate drugs, the majority of STD clients can be treated by primary care workers at their point of first contact with the health-care system.

For trainers, the key to implementing the syndrome approach is the flowchart. Flowcharts, also called algorithms, bring together practical and scientific information for clinical decision making. Recommended treatment is based on knowledge of the most likely causative agents, distinguishing features of the disease and known patterns of drug resistance *(see Chapter 8)*.

The use of flowcharts does not require that the health worker have an in-depth knowledge of causative organisms and drug sensitivities in order to arrive at a diagnosis. Ideally, prevalence and antibiotic sensitivity studies using regional or country data would have preceded the development of flowcharts for local use. Selected health workers presented with the data from these studies can arrive at a consensus as to the content of the flowcharts. If this approach is used, it is more likely that there will be a sense of ownership of the guidelines on the part of local health officials and health-care providers. Consensus meetings to review data and develop guidelines can be considered training in a sense, and those involved can be used in training others. This approach can greatly enhance the work of the trainer in promoting what is, perhaps, a new approach to the treatment of STDs.

The STD management flowcharts form the framework for the training that will also address the reasons for the flowchart recommendations, the clinical history and decision-making process, and the education component. One approach to promoting an understanding and familiarity with the flowcharts is to request that training participants, using the flowcharts, work on case studies prior to the training and during the training. Case studies can be used as pre- and post-tests, and for continuing education.

The Characteristics of Effective Training

This section discusses key characteristics that STD managers should look for when reviewing a training program or when seeking a consultant or organization to implement a training program. These training criteria are proposed as indicators of the appropriateness of a training program for the experienced health-care worker who also is an adult learner. The concepts might be new for some STD managers and the STD experts who may be asked to conduct the training. Many managers and physicians were educated or trained in traditional settings using didactic methods that are inappropriate approaches to training adult learners.

The training is competency-based

One characteristic of training that is intended to impart skills, such as training in STD management, is that the training be **competency-based.** This means that the training provides skills and knowledge needed to accomplish a specific task—in this case, STD management. The success of the training is judged by how well the skills are performed by the training participants after the course has ended.

How will an STD manager know if the training is competency-based? He or she can look at the agenda to determine if there is time for actual practice of skills. In an STD management course this practice would take the form of activities such as case studies and role plays. If the training agenda has a series of lectures with no practice, the STD manager should question whether the training will result in skill acquisition, which should be the goal.

The training follows principles of adult learning

HOW ADULTS LEARN

1. Respect
2. Immediate Use
3. Experience
4. Safety

Effective adult training takes into account that the participants have experience and opinions that need to be respected and valued. This can be done by providing opportunities for the participants to share their knowledge and skills with the trainer and with one another. Discussions should be encouraged in which participants demonstrate problem-solving and have the opportunity to cite experience from which the knowledge is applicable to real situations.

Other principles of adult learning include:

Needs assessment: This results in a training design that takes into account the level of understanding, readiness and experience of the participants. Listening to learners' wants and needs helps shape a program that is immediately useful. The question the manager and the trainer(s) should ask is: who needs what as defined by whom?

Respect: This includes culturally appropriate courtesies and an attitude on the part of the trainer that conveys value for the participant as a person, a learner and an experienced worker. Respect includes a concept of the learner as the subject of his/her own learning.

Safety: Participants feel safe in the learning environment. They are not worried that their input will be ridiculed or judged harshly. It is the trainer's responsibility to provide a respectful response to participant input, thus enhancing the participant's feeling of safety. This will result in increased participation.

Sequence and reinforcement: The content and skills of the course are programmed in an order that goes from simple to complex and from group-supported to solo efforts. Reinforcement is the repetition of facts, skills and attitudes in diverse, engaging and interesting ways until they are learned.

Praxis: This involves doing something with new knowledge, practicing new skills and then reflecting on what has just been done. Case studies that invite description, analysis, application and implementation of new learning are an example of praxis.

Ideas, feelings, actions: There are three aspects of learning: ideas or knowledge (cognitive), feelings (affective) and actions (psychomotor). Training adults is more successful when all aspects are addressed in the training methods. Briefly, lectures are appropriate for conveying ideas; role plays and discussion for affective aspects; and practice, including role plays, case studies and problem-solving, for the psychomotor aspect.

Immediacy: Adult learners need to see the immediate usefulness of the skills, knowledge and attitudes that they are working to acquire.

In STD training, health-care providers are required to be competent in comprehensive management of STD clients, including clinical care, health education and counseling. Competency-based training equips people with skills they can use for specific tasks.

One of the truisms of learning is that we retain little of what we hear, a bit more of what we read, more of what we do and most of what we discover for ourselves. Building on this principle, participatory learning actively involves people and thereby ensures that they retain more of what they learn. In this participatory training style, active methods such as demonstrations, case studies and discussions are used more often than traditional lectures.

I hear and
I forget

I see and
I remember

I do and
I understand

–Confucius

Participatory learning is based on the principle that the trainer poses problems for the learners that they work on together to solve. This builds on the principle that the trainers come with experience and knowledge. The methodologies that actively involve the participants are the most useful. Thus, lectures, which are used almost exclusively in traditional approaches to education, are used as little as possible when conducting participatory training.

PLANNING THE TRAINING

In planning the training of health workers in STD case management, it is useful to perform the following steps:

- Conduct a training needs assessment.
- Work with a local team to determine the criteria for course participants.
- Set course objectives
- Set training session objectives and design.
- Select training methods appropriate to the content of each session.
- Outline the resources for supplies, personnel and facilities needed, and specify the budget.
- Develop an evaluation plan that includes participant follow-up.
- Prepare a training proposal if funds are needed.

If possible, in developing a training plan, it is good to work with a team composed of the STD manager, a provider and an experienced trainer. This team approach ensures that the training is designed and implemented to maximize adult learning, meets the needs of the STD program, is technically sound and can be accomplished.

CONDUCTING A TRAINING NEEDS ASSESSMENT

In planning competency-based training, it is important to identify the skills participants will need to manage patients according to the syndromic approach and determine the current level at which they are in command of these skills. In addition, the need for specific skills at different levels must be defined according to the setting in which the worker practices. For example, health workers in a primary care setting might have experience managing STDs using the clinical approach and minimal practice or training in using the syndromic approach and doing prevention counseling. On the other hand, workers in a family planning clinic might have little experience with STDs and all other components of STD management. The course would have to be designed to meet the needs of both types of participants if they were to be included in the same course. In other words, the setting in which the participants practice, including constraints and available resources, is information that should inform the training plan as well. Assessing the skills being performed competently as well as those that need strengthening is essential.

To determine which skills must be addressed in the training, it is necessary to define the function the participants must perform in their work setting. The functions providers must be able to perform in order to use the syndromic approach to the management of STDs are several. Though not exhaustive, the following is a sample list of these functions:

- History-taking and risk assessment
- Recognition and management of signs and symptoms and complications of STDs
- Patient education and preventive counseling

The performance of these functions requires more than factual knowledge. There are skills germane to each of these functions. For example, history taking requires interviewing skills, and patient education for STD prevention requires skills in condom demonstration and behavior change advising.

Assessing participants' current practices in STD management can be done by interviewing health-care providers, supervisors, clients and other community members about what is currently done in managing STDs and how current practices are perceived in terms of effectiveness and acceptability. This information can be used with information from clinic records about the way in which STD clients are currently managed and what areas need to be improved. With the aid of checklists, direct observation of health-care providers can help determine how clients are treated. Checklists can be used in assessing how and what elements of the history and physical examination are currently performed, how the promotion and distribution of condoms is being handled, and what the prescribing practices are.

In addition, it is important to assess what is being taught in the basic curricula of medical and nursing schools in the public health approach to STDs. Incorporating concepts of syndromic management and prevention counseling into basic programs could serve to improve overall practice.

OVERALL COURSE CONTENT

This section addresses the general areas of STD case management that are appropriate for inclusion in training programs in most countries, with individual variations. The major content areas that the training should address are:

- STDs: transmission, control and the syndromic approach
- Prevention education and behavior change
- Partner management and reporting systems

STDs: transmission, control and the syndromic approach gives the health-care worker a background in the public health perspective on STDs. Whereas many training workshop participants may have experience treating individual patients with STDs, many will not have had the opportunity to learn about STD epidemiology and what is required at the community level to change the prevalence of STDs. This content is important in motivating participants to use the syndromic approach because it places the problem of the STD patient—the individual infection—in a community context. The provider is challenged to do more than deal with each individual case, but to be a part of a larger community effort involving partner management, reporting and prevention of repeat infections.

In addition, many providers who have been using the clinical or etiologic approach to STDs have a strong need for information about the local STD prevalence, related risk factors and drug resistance issues, including specifics about which locally available drugs are the most effective. Information about local policies and procedures for partner management and reporting is also needed.

Prevention education and behavior change is a critical part of the case management approach, though it is often omitted in busy clinics. While it is understood that many clinicians are not oriented to counseling or patient education, it is important that managers and providers be aware of the important impact these efforts have on behavior change in regard to STD prevention and treatment. Although clinicians and managers

may not do the actual education and counseling, their support and facilitation of others who are trained and interested in this are critical.

Partner management and reporting systems are essential to the effective control of STDs. All reporting, including any information regarding partners, must be confidential. The training content should address partner notification and reporting in the general context of how they fit in with prevention and control efforts, and there also should be specific instruction on local policies, procedures and reporting systems.

TRAINING OBJECTIVES

The course objectives should be behavioral in nature in the sense that they should state what the learner should be able to do at the end of the course and be measurable. Objectives should describe behaviors participants will be able to demonstrate, skills they will be able to perform or knowledge they will be able to use as a result of their course participation. The described behaviors should be measurable, feasible and relevant. For example, instead of using the verb "to know," which cannot be measured, trainers might use verbs such as "to list," "to describe" or "to discuss" that are measurable. For example: "At the end of this session, participants using a flowchart will be able to diagnose and manage men with urethral discharge." Here are some examples of possible course objectives:

- Participants will be able to recognize and manage appropriately the STD syndromes of urethritis, genital ulcer disease, vaginal discharge and pelvic inflammatory disease.
- Participants will be able to describe and demonstrate correct condom use.
- Participants will understand the importance of patient confidentiality and be able to cite ways to ensure it.

These more general objectives can be broken down into more specific objectives for each session. At the beginning of each course and each session, the trainer should explicitly review the objectives with the participants.

TRAINING METHODS

As mentioned above, adult learning methods are likely to be the most effective when training experienced health-care workers. It is recommended that the trainer employ participatory techniques that actively engage the learner. These might include small group discussions, demonstrations, role plays, case studies and simulations.

In planning the training, the trainer must identify the most effective teaching method for the type of content being covered in a session. In other words, the method should match the domain of learning (is the domain of learning cognitive, affective or psychomotor?). The lecture is a method often used in medical training workshops. Its methods are really only suitable for the transfer of factual information. It is not the most effective way to teach skills such as history-taking, physical examination, problem-solving or diagnosis. These are best addressed by methods such as case study, role play, group discussion or actual practice with feedback. *(The areas of learning domains and teaching methods are discussed in greater detail in Chapter 10.)*

Trainers encourage and facilitate the educational process by illustrating learning experiences, providing feedback, summarizing important points, challenging participants and pacing the introduction of new material. Supervised field experience during or shortly after a workshop may be the single most important way to acquire the skills, attitudes and knowledge needed to use the STD flowcharts. Such field experience involves having a trainee manage patients with STDs in a clinic in collaboration with a trained supervisor. Follow-up supervisory visits should be planned for in conjunction with the STD program manager and are an essential part of training.

To be effective, field experiences need to be carefully organized. The supervisor should be trained in appropriate supervision techniques and should use observation checklists to assess the trainees' work. For

example, in Tanzania, that the trainees spend three to five days immediately following a workshop under the watchful eye of a trained supervisor has resulted in a marked increase in their effectiveness. Follow-up supervision at a later time, such as three or six months after the training course, has also proved effective.

SPECIFIC TOPICS IN THE MAJOR AREAS OF COURSE CONTENT

STDs: transmission, control and the syndromic approach: The level and amount of detail in which this area is addressed is determined by the needs assessment and should take into consideration factors such as the background of the health workers. The needs assessment is the key to targeting the level at which the content is taught and the amount of detail appropriate for the participants. In general, the content in this session includes:

- Local epidemiology of STDs
- Factors affecting transmission of STDs
- The relationship between STDs and HIV
- The complications of STDs
- Factors affecting STD risk and prevention
- Local beliefs and practices about STDs

Clinical management of STDs using the syndromic approach: The manner in which this area is dealt with is critical to the success of the course. It is understood that participants have been practicing in the best way that they know how. Trainers should be sensitive to the difficulties of suggesting that clinicians change the way in which they approach their professional practice. Exploring attitudes toward the syndromic approach might help avoid pitfalls of participant resistance. In general the syndromic approach should be put in the context of public health goals and not couched simply as an approach that works when there are not enough resources to do STD laboratory tests. The aspects of clinical management using the syndromic approach that should be addressed include:

- The syndromic vs. clinical vs. etiological approaches to managing STDs
- History-taking and the physical exam in assessing patients for STDs
- The syndromic approach and how it fits into a public health approach to STDs
- The use of flowcharts in managing STDs (advantages, disadvantages and techniques for successful application)
- Risk assessment for STDs
- Specific STD syndromes: assessment and management of vaginal discharge urethral discharge, genital ulcers, lower abdominal pain, infected eyes in newborns

It is understood that participants should already have a basic knowledge of male and female anatomy and the general facts about the transmission of sexually transmitted diseases. However, many will have been trained years ago and may have had little opportunity to update their knowledge. Thus, they might not be familiar with more recently identified STDs such as chlamydial infection, or with new antibiotics. In addition, many providers might not have experience, personal or otherwise, with condoms.

Patient education for behavior change: The goal of behavior change and communication strategies is to prevent STDs. Communication strategies are important in teaching new information and correcting old myths *(see Chapters 4 and 10)*. And since anyone being treated for an STD remains at risk of acquiring another one, the treatment process itself provides an excellent opportunity to educate to reduce further episodes. Patient education is a crucial part of any STD control program and, therefore, needs to be part of every contact between a health-care provider and an STD client. The focus of patient education for behavior change is in the following:

- Enhancing health-seeking behavior. (People seek out health care when it is of good quality. So first improve the quality of health services provided.)

- Data about current STD prevalence and utilization patterns of health services
- Facts about condom effectiveness (and, if possible, a demonstration of condom use), posters, brochures and videotapes *(see Chapter 5)*
- Information about the importance of complete patient management, not just drug treatment. (Management for each client should include the 4 Cs: contact tracing, condom use, counseling/education and compliance. Clients need to know how they acquired the infection, about symptoms so they can report early for treatment, and about the importance of completing the full course of treatment.)

Behavioral skills include:

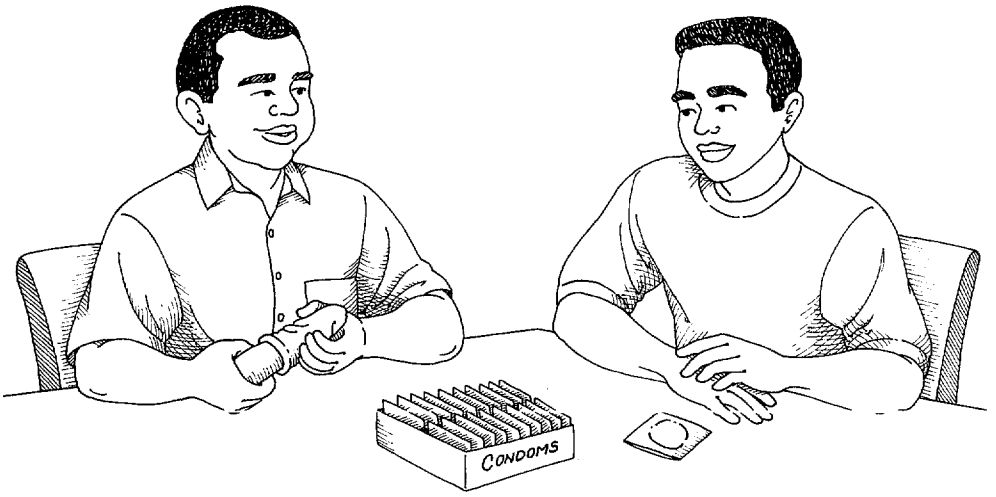
- Ability to talk about sexuality and sexual behavior with self-confidence, so people are comfortable discussing these issues with the health-care provider
- Interpersonal communication skills to facilitate client relationships, speaking the same language and being able to personalize health messages, and the ability to project a positive attitude toward STD clients
- Counseling skills, including how to assess a client's risk during an interview, how to negotiate risk reduction, and how to provide client-centered counseling. (Counselors need to allow for client differences in beliefs, values and behaviors.)
- Ability to demonstrate condom use and assist in client acceptance of condoms

- Early symptom recognition and treatment
- The 4 Cs: contact tracing (or partner referral), condoms, counseling/education and compliance

The content that should be addressed in this area covers the knowledge and skills that health-care workers need to influence client behavior. This includes cognitive information and behavioral skills. (Full discussion of the important messages to be communicated to STD clients can be found in Chapter 10.)

Cognitive information includes:

- Knowledge of the social and behavioral elements related to the patient population, causative and preventive behaviors, and an awareness of knowledge, attitudes, behaviors and myths related to STDs *(see Chapter 13)*



Teaching methods for these topics should provide skills practice through role play and case studies. Sample role plays can come from the participants themselves. The role plays should be brief with very clear directions from the trainer about the communication skills that are being practiced followed by feedback that addresses what was done well and what might have worked better. The feedback should be directed to the specific behaviors demonstrated. The element of safety is critical to the use of role plays. The trainer needs to facilitate in such a manner that participants feel confident and are given feedback in a respectful way.

Topics in the workshop that address the information and skills that providers need include:

- Influences on health behavior: social norms, media, beliefs and attitudes
- Why sexual behavior is difficult to change
- Approaches to behavior change
- The role of the health-care provider in behavior change
- Strategies for motivating patients to change behavior
- What patients need to know about STDs and how to explain it
- How to improve compliance with treatment recommendations
- Overcoming barriers to compliance with drug treatment instructions

Community health workers can help spread the message that early treatment is important. They can also demonstrate how to use condoms, help make condoms more accessible and initiate discussions about sexual behavior in the community. The STD training programs should teach health workers the skills they need to work with communities and ensure that health-care providers have an opportunity to use their new skills.

Dealing with patients with STD, especially HIV/AIDS, can cause great concern and even fear in health workers. Unless such fears are dealt with, the knowledge gained in the workshop will not be put to use. Recognizing and discussing such fears can help put them in perspective.

Partner management and reporting systems: Partner management issues *(see Chapter 11)* are a part of the prevention counseling session as well, but the systems put in place locally to deal with partner tracing or contact information are additional aspects that should be addressed. In addition, reporting of STDs is an important issue in STD control. The data gained at clinics becomes a part of the national statistics. This then helps to set priorities in dealing with STDs, identifying essential drugs and tracking the success of prevention and control interventions.

The general topics that should be included are:

- The importance of partner management to STD control
- Approaches to partner notification
- Working with patients to notify partners
- Reporting:
  - Reporting STD cases: local approaches, local needs
  - Confidentiality issues, interviewing, partner management and reporting

Box 1

SAMPLE LESSON PLAN

Session *Urethral Discharge*
Time *60 minutes*

Objectives

At the end of this session, participants will be able to:

- diagnose, treat and manage men with urethral discharge using a flowchart.

Background

Participants have already covered the reasons for the use of flowcharts, their advantages and limitations. This session focuses on teaching the use of flowcharts for treatment of genital discharge in men. Much of the technical information that participants need to know about discharges can be conveyed in small groups when the case studies are being covered. Make sure that participants have enough time to work through all the case studies and discuss them.

Content Outline

Introduction to flowchart	5 minutes
Case studies in small groups	30 minutes
Plenary discussion	20 minutes
Summary	5 minutes

Resources

Discharge case study sheet, answer sheet, flowchart, butcher paper, marking pens, flip chart, masking tape and pointer. Poster with urethral discharge algorithm. Hand-out on **Signs and Symptoms of STD.**

Reading

STD manual

If a reporting form exists to monitor STD cases, the program manager should ensure that it is consistent with the training materials. It is not uncommon for the training to be oriented to the syndromic approach and the reporting forms to specify a specific etiologic diagnosis. The completion of these health information system forms should be included in the training.

Many countries have a national health information system form for all types of visits. Modifying this form to reflect the syndromic approach is neither easy nor inexpensive. Often there is no optimal solution to training in syndrome management and using old reporting forms. The need for the information *(see Chapters 14 and 15)* and the extra burden to the health provider of additional reporting forms if the current ones cannot be easily modified needs to be taken into consideration. (See Appendix 1 at end of chapter, an example of a patient encounter form that reinforces the syndromic approach.)

TRAINING SESSION DESIGN

Once training needs have been assessed, using the session content as outlined above, trainers can design session objectives, contents and methods. Each session design consists of a title, objective(s), background section, outline of content and methods, time required and a list of resources needed. (See Box 1 for illustration of sample lesson plan).

Many of the books written about STDs are inaccessible to the majority of health-care providers because they use highly technical language and are expensive. The World Health Organization (WHO) and several countries have developed STD training manuals. Some are written to be used outside of a workshop setting. Given the time and expense of most workshops, alternative approaches are recommended when possible. Some examples of alternatives are self-learning modules, similar to the new WHO manual on STD case management. Self learning modules offer options such as: (1) individual review of the

manual, followed by group meetings with a facilitator, or (2) group review of the manual with a facilitator. These sessions can take place for an hour or two on a work day at the clinic or on a day away from the clinic monthly, until the content is covered. Much of this depends on the manner in which syndromic management is being introduced to the clinic setting. If there is rapid implementation planned, this might not work, but if there are providers employing the syndromic approach and others are being gradually "brought on board," this long-term training approach might work.

The recommendations in manuals written for individual countries can be adapted to the local circumstances in areas such as antibiotic recommendations and referral patterns. Many of these manuals have facilitator guides that provide background information on each topic as well as suggestions for optimal use of the session.

Trainers may have to develop additional lesson plans to address specific needs that become evident during training. In Kenya, for example, trainers noted that health workers believed high-risk sex behavior was a problem for high-risk groups but not for others. To address this misconception, exercises were developed in the classroom to dispel this notion and to raise awareness of broader personal risk.

When incorporating new material or combining sessions, trainers often try to cover the same amount or more material in less time. As a result, none of the material is absorbed fully. To avoid this mistake, trainers should review the learning objectives each time they revise a session. It is also important to allocate time in the training schedules for writing reports of the workshops and for training the trainers. A decision should be made on whether to have an orientation workshop prior to training. An orientation workshop can ensure that the key people involved are aware of the program, advised of their roles and supportive of the health-care providers.

SELECTION OF COURSE PARTICIPANTS

In developing countries, the majority of STD clients are treated by auxiliary health workers. However, in many countries, doctors in private settings also provide care for many people with STDs. If new approaches to case management are being used, private practitioners might want to learn about them. Furthermore, doctors can be more supportive of the efforts of primary health-care workers if they are aware of their activities. Doctors also can be influenced to provide more and better STD health education and counseling.

Physicians can be contacted through their professional associations. Presenting a paper at a conference, mailing out pamphlets and posters, and holding short workshops are other ways to reach out to physicians.

Training in sexuality and sexual behavior appears to work best in mixed groups of male and female health workers. Such groups reflect the way in which people live and work. Experience suggests that mixed groups can stimulate honest interaction and openness on the issues surrounding sexual behavior, but this is something that should be decided at a local level.

THE ROLE AND SELECTION OF COURSE TRAINERS

To sustain skills learned at the workshop, it is important for health-care providers to have continuing support and supervision in the field. Training does not stop when the work ends. It is an ongoing, life-long process. If possible, select as trainers people who will be supervising the health-care providers. This will also help supervisors update their own knowledge through training of trainers sessions.

Adult education and participatory learning methods are often new to the trainers, so it may be necessary to provide training of trainer sessions. It is often useful to involve as trainers those who already have training skills, such as tutors from basic training schools or trainers from nongovernmental organizations that operate primary health-care projects. These trainers can share their skills and experience in training health

workers with others who are learning to train for the first time. In addition, as a result of their exposure to the new STD training material, tutors may be able to incorporate some STD workshop material into classes they already teach or stimulate curriculum change within their schools. And it may be possible to involve them in regional refresher courses, augmenting the input of the district health team and health unit supervisor.

THE ROLE AND SELECTION OF THE COURSE FACILITATOR

In order to have a well-organized course that consistently follows the session designs and uses participatory methods, with attention to the safety and comfort of the participants, it is important to select a skilled facilitator. The role of the facilitator is more global than that of the individual trainers, a term used here to refer to presenters. The facilitator should be familiar with the course and, ideally, will have worked on its design. The facilitator should be skilled in ensuring that the trainers and the participants progress toward the course objectives, play a key role in maintaining a participatory format and deal with issues as they arise. For example, if it becomes evident that participants are having difficulty with the content or are hesitant to participate, it is the role of the facilitator to intervene with the trainers to resolve the matter.

In many situations the facilitator might be referred to as the lead trainer or course organizer. Whatever the term, the presence of the facilitator is key to the success of the course. The person should be respected locally and be knowledgeable, though he or she does not necessarily have to be considered an STD expert. The importance of diplomatic, group management and training skills supersedes the importance of technical knowledge for the purpose of the role as course facilitator.

RESOURCE NEEDS

Both the human and financial resources needed for a training session should be identified. Scarce training resources can be stretched farther through cooperation with others. In Uganda, for example, regular coordination meetings involving the Expanded Program of Immunization as well as the Continuing Education, Control of Diarrheal Diseases and Essential Drug programs, resulted in optimal use of limited training resources. Coordination of training by these programs minimized the time required for district teams to be absent from their posts for training. It also eliminated duplication of content in training courses.

If other training programs such as the Expanded Program for Immunization or the Essential Drug Program have carried out training of trainers in a district, potential trainers already may have acquired basic training skills and may only need to be provided with STD material. If a rural health training school is nearby, its tutors could be involved as trainers.

Early attention to the venue of workshops, per diems and out-of-pocket expenses can help managers avoid problems. Managers should be aware of what other training groups working in the country are doing.

The support and supplies needed for the application of new skills should be in place by the time health workers return from their training so they can use their new knowledge and skills immediately. These resources include a regular supply of drugs, a functioning referral system, a health information system and trained supervisors. Needles, syringes, test tubes, gloves and specula, as well as a way to sterilize them, may also be needed, depending on the nature of the algorithms to be used. Also, it is important to have on hand a supply of materials that reinforce the training such as flowcharts, wall posters, and provider-patient encounter forms.

Box 2

STD/AIDS Fishbowl

Objective

To clarify knowledge about STD/AIDS and apply this knowledge in an advice-giving context. To identify gaps in knowledge or areas where confidence is lacking.

Resources and time

A large room and 40 "problem cards." One hour.

What you do

Hand out one "problem card" to each group member. Half the group forms a circle facing outward. The other half forms a larger circle around them, facing inward, so that each person has a partner. Those in the inside circle are "counselors," offering advice to others. Ask each member of the outer circle to tell their problem to their partner in the inner circle. The "counselor" gives the best advice he/she can think of. Allow three minutes for this to happen.

Each outer circle person moves to the inner circle person on their left and repeats their problem until each "counselor" has been asked to advise on every problem. The inner and outer groups change places. The former "counselors" ask about the problems on their cards until everyone has had a turn at being both a "problem presenter" and a "counselor."

Reassemble the whole group and ask each member in turn to explain what their "problem" was, the advice they found most helpful and why.

Sample "problem card"

A pregnant woman comes to the antenatal clinic and is found to have a positive syphilis test. She denies having sex with anyone except her husband. She is afraid to tell him to come to the clinic.

Like outcomes

By having their advice evaluated and by receiving advice from others for a problem and evaluating it, participants gain insight into messages that work and why.

(STD/AIDS Fishbowl is adapted from AIDS Exchange, WHO, 1991, No. 2)

One example of resources is sample exercises for trainers to use. Especially for trainers who are accustomed to using the lecture method, it is helpful to provide exercises that make it easier for them to use a more participatory approach. These can be included in the lesson plans. An example of a tool for this type of training and for clinical practice is the AWARE Scorecard, which can be used to raise awareness about the risk of STDs and AIDS *(see Appendix 2).*

THE EVALUATION PLAN

To get the best results from training, managers should ensure that evaluation occurs in several different ways. Possible evaluation methods include knowledge pre- and post-tests, before-and-after attitude assessment, skill evaluation, feedback from participants and facilitator evaluation. Evaluation indicators should include process measures, such as the number of workers trained and the number of courses held, and outcome measures, such as the number of clients being managed appropriately and the number of contacts brought in for treatment.

Evaluating gains in knowledge: pre- and post-tests

Measurement of knowledge gained and its use in solving problems can be evaluated through multiple choice questions given before and after training. It is useful to have one or two questions on each topic covered in the workshop. Detailed item analysis of each question can help trainers determine whether there are problems with the question itself or whether the material has not been learned. For example, detailed item analysis assesses the number of people who get the question right to start with and wrong afterwards, or wrong at the beginning and right afterwards, and so forth. Getting the question wrong afterwards could indicate that the manner in which the material was presented generated confusion rather than greater understanding or clarity. Trainers can measure the difference between the pre- and post-test scores to calculate the increase or gain. It is also possible to calculate an "adjusted" gain by dividing the gain for each person by the maximum possible gain he or she could have achieved.

$$\text{ADJUSTED GAIN} = \frac{\text{POST-TEST} = \text{PRE-TEST SCORE}}{100\ \% - \text{Pre-test score}} \times 100$$

Box 3

Observation Checklist for Genital Ulcer

1.	Introduction	Yes	No
	Friendly tone		
	Privacy established		
	Exam room appearance		
2.	History	Yes	No
	Pain		
	Discharge		
	Sexual contacts		
	Condom use		
	Previous STDs		
3.	Physical exam performed	Yes	No
4.	Treatment	Yes	No
	Explanation of diagnosis		
	Correct drugs prescribed		
	Correct dose & duration prescribed		
	Contacts referred		
	Condom use demonstrated		
5.	Follow-up notes/comments		

Measuring Changes in Attitude and Perceived Competency

Provider competency in fulfilling their role in STD management, as well as attitudes and perceptions about patients, can be measured through focus group discussions, observation and personal interaction with participants. A brief, standardized attitude questionnaire may also be useful. To measure perceived competency in performing the skills described in the behavioral objectives, it is useful to do a before and after self-rating by participants. Examples of several appropriate statements include:

- I am comfortable using flowcharts to treat patients with a vaginal discharge.
- I am comfortable conducting a risk assessment with patients.
- I can identify the major types of STDs that cause vaginal discharge, urethral discharge and genital ulcers.

These statements are then rated from "agree strongly" as a 5 on the scale, to "disagree strongly," 1 on the scale. The goal is that perceived competency will increase from the pre-workshop to the post-workshop measure.

One of the most important ways to ensure that health-care providers have been well trained is to visit them some time after the course and observe how they manage STD clients. Trainers or supervisors should use an observation checklist *(See Box 3)* to help them provide objective feedback. After observing a health-care provider's compliance with the items on the checklist, the supervisor then should discuss each item with the

provider and give an objective assessment. Items that have been done well and areas that need improvement should be reviewed.

Health-care providers can assist in preparing the observation checklists. Checklists allow supervisors to provide objective feedback and should be limited to no more than nine items. The presence of too many items only discourages both the supervisor and health-care provider. When a health-care provider has demonstrated mastery of the first nine items, other areas can be added. Key items for an observation checklist could include the following:

- Taking a relevant history, and conducting a regional physical examination of the genital area related to the presenting symptoms in men and women
- Examining the eyes of a newborn baby
- Applying ointment to eyes of the newborn
- Conducting an abdominal exam in women with abdominal pain to assess tenderness, guarding and rebound tenderness
- Diagnosing and treating key STD syndromes using flowcharts (e.g., vaginal discharge, urethral discharge, genital ulcers, lower abdominal pain in women and infected eyes in newborns)
- Encouraging clients to:
  - seek treatment early for STD symptoms
  - use condoms
  - refer partners
  - avoid self-medication
  - complete the full course of treatment
  - refrain from sex until cured
- Counseling clients on sexual risk reduction

Assessing health-care providers at their work sites also will provide information that can be used in future training sessions, such as additional topics or specific areas that need more emphasis.

Participant Feedback

Participant evaluations at the end of the workshop can be detailed and comprehensive, covering individual sessions and daily activities, and indicating degree of satisfaction with the training.

During the course, participants should be encouraged to comment on individual sessions as well. Trainers should keep such feedback simple and vary the format and style to bring out the main points that need to be addressed during the course. For example, they could ask what was most and least useful about one session and, after another session, whether trainees' opinions were valued and how. Suggestions can help trainers make changes during the course and improve future courses. Use of forms may improve feedback. Many trainers have found it useful at the end of each day to have the facilitator lead the group through a summary of "what went well" and "what didn't go well," using a flip chart to keep track.

Another useful device to capture issues and questions during the course of the workshop is to have a piece of flip chart paper on which participants and trainers can write unresolved or end-of-the-day questions that need to be addressed prior to the conclusion of the course. This frees the trainer and facilitator from having to remember each one and provides participants with the sense that the questions they have raised are important and respected.

Trainer and Facilitator Evaluation

Besides getting feedback from participants, trainers and facilitators should evaluate themselves using self-scoring lists. They also should provide feedback to one another in a supportive way so they can assess how the course is going and make changes as needed. Daily facilitator meetings not only help keep training on track, but also provide an opportunity for facilitator interaction and growth.

Participants also can evaluate the following course components:

- Venue
- Organization
- Quality of presentations
- Quality of participant participation

In evaluating trainers, participants should be directed to assess elements such as clarity of presentation, interest in the presentation, and responsiveness to participants' questions and concerns.

SUCCESSFUL TRAINING: KEY ISSUES

FOLLOW-UP AND SUPERVISION

Training that is a one-time effort or that is not put into practice can waste precious human and financial resources. As mentioned earlier, the support of clinic supervisors is critical to the impact of the training on actual practice and the improvement of STD case management. In addition, supportive supervision can contribute significantly to the providers' continued application of new skills and principles. When participants are not able to apply new skills and information, they can become demoralized and training can lose its credibility. Thus, during the planning phase, the STD manager, clinic supervisors and trainers should plan a follow-up to the training.

If necessary, the supervisor should be trained in the skills and attitudes needed to provide appropriate, supportive feedback. Supportive supervision means that a supervisor gives encouragement and positive feedback, identifies weaknesses and assists health-care providers in carrying out what they have learned. Supervision, which is influenced by the local situation, requires familiarity with the local situation, and empathy with health-care providers.

Although it is generally recognized as the most important aspect of ensuring quality care, supervision is often neglected. This may be a result of constraints on transport and/or on adequate staffing. Success may be achieved by using exceptional, experienced workers as supervisors.

In many STD control programs it may be possible to have health-care providers from the STD referral center visit outlying units to augment supervision. One caution about using single-purpose health workers as supervisors for multipurpose primary health-care workers is that they may undervalue and underestimate the time and effort required for other aspects of a multipurpose health worker's job description.

LENGTH OF TRAINING

In most primary health-care units, STDs account for less than 10 percent of clients' health problems. Health-care providers who are required to manage 20 or more common diseases cannot spend too much time on one disease. In addition, governments generally cannot afford to extend continuing education programs to all health workers or to upgrade their skills regularly with lengthy training programs. What is too lengthy varies from country to country, but often any course that exceeds three to five days is considered excessively long. To maximize support for STD training, workshops should be efficient and accommodate clinic demands. As mentioned above, alternative approaches to workshops are also recommended. Periodic seminars over a defined period with self-study sessions are one option.

To illustrate, the two-day in-service training for health workers in Kenya included a brief exposure to the following topics: public health importance of STDs; management of ophthalmia neonatorum, genital ulcers, vaginal and urethral discharge, abdominal pain in women and antenatal syphilis screening; team building; condom demonstration; clinic simulations; communicating health messages; and community interaction. It was possible to introduce and provide some practical exposure to each topic.

Often trainees will ask for more time and trainers often may feel they need more time. But much can be covered in two to three days that can improve client care. This is true especially when training is followed by field experience and continuing supportive supervision.

CONTINUING EDUCATION

Learning is never over. It is a lifelong commitment. Here are two techniques to stimulate continued learning:

- During the workshop, identify areas in which participants want to continue to work such as developing their counseling techniques, or learning more about STD prevalence or improving reporting forms. Time can be set aside during a meal or break at the training to brainstorm ways in which participants can continue to learn.

APPENDIX 1

❍ **vaginal discharge**		❍ vaginitis		
❍ risk score positive (2 or more)		❍ cervicitis		
❍ with **abdominal pain**	❍ abdominal tenderness ❍ cervical motion tenderness	❍ pid		
❍ late period ❍ pregnant or recent pregnancy (6w)	❍ rebound ❍ guarding	❍ obs/gynae referral	❍ referral	
❍ **urethral discharge** ❍ burning with urination	❍ discharge	❍ urethritis		
❍ **genital ulcer**	❍ ulcer ❍ multiple blisters ❍ bubo	❍ genital ulcer	❍ drainage	

number: _____

sex: F M

age: _____ 1

status: S M U D W 1

partner has symptoms? Y N 2

#of partners in last 3 months? Y N 1

risk score _____

if contact:
referral number: _____

symptoms? Y N

condoms demonstrated
condoms dispensed

partner referral
coupons given

source of infection:

- Ask trainees to consider how they can continue updating their knowledge and skills. For instance, they may decide to meet for half an hour each month and ask a staff member to review the management of a difficult case.

Distance learning courses have been very effective in sustaining learning that began at short workshops. In Uganda, during times of insecurity when the postal and telephone service did not work and health units were closed, health-care providers continued their distance education lessons. Local arrangements kept the lessons moving between the district health offices and the Center for Health Manpower Development.

Distance learning includes correspondence courses, radio shows and face-to-face workshops. If distance education is already provided for health workers in your country, discuss the possibility of developing an STD course based on your training. If STD training is not offered, stimulate interest and activity in the area. The African Medical and Research Foundation (AMREF) in Nairobi, Kenya, an NGO specializing in primary health care, provides distance education courses to health workers in several East African countries and is currently developing STD courses. Short refresher courses of one or one half day can be used to upgrade and solidify skills, discuss problems and enhance motivation every one to two years.

TRAINING FOR THE PRIVATE SECTOR

Although private sector practitioners may be difficult to reach and often lack the time to attend training sessions, making available continued medical education and skills upgrading to them remains essential.

Possible approaches to the challenge of providing training for private sector practitioners include:

- Working with national medical associations
- Working with training centers to award diplomas or other forms of recognition
- Providing mailings in the form of newsletters and self-instructional manuals
- Writing key articles for regional or national journals

REFERENCE MATERIALS

The availability of books is an important determinant of continued learning. If possible, clinics should provide simple reference manuals for the health units. Currently, programs in many countries are developing expertise in local production of such manuals through the Health Learning Materials Network of WHO.

Ongoing access to sources of current information about STDs, including HIV/AIDS, is critical for anyone planning an STD training course. Sources of training materials, including books, are provided at the end of the chapter. Also listed are a number of newsletters with current information, suggestions and articles from many countries that include information about STD and AIDS. Many are free in the developing world.

APPENDIX 2

Risk assessment is conducted one-on-one between the health-care provider and client. It is done interactively, drawing on what the client knows and thinks. A trainer can model how to help providers put risk assessment into a positive context by working with them to develop an introductory statement that does the following:

- Ensures confidentiality
- Expresses empathy that the topic is sensitive and difficult to discuss
- Stresses the importance of accuracy

This discussion is a vehicle for helping the client come to believe that the risk of infection is important. It also assists the client in accepting that his personal behaviors are directly connected both to real risks and to risk reduction.

Counseling about risk reduction is undertaken after risk assessment has been completed. The AWARE Scorecard on risk reduction may be helpful as it outlines in descending order the main risk-reducing sexual practices.

Aware Scorecard Sexual Risk Assessment Form

How many sexual partners have you had:
in the last week? _____
in the last month? _____
in the last year? _____

Do you have a steady sexual partner (sex with him or her three or more times)? ❍ Yes ❍ No

Do you have more than one steady partner? ❍ Yes ❍ No
If yes, how many? _____

Have you ever paid someone to have sex with you? ❍ Yes ❍ No

Have you ever been paid by someone to have sex with them? ❍ Yes ❍ No

Have you ever had a sexually transmitted disease? ❍ Yes ❍ No

If yes, have you been diagnosed with the following *(check as many as apply)*

	Once	**A few times**	**5 or more times**
Syphilis	_____	_____	_____
Gonorrhea	_____	_____	_____
Chlamydia	_____	_____	_____
Trichomonas	_____	_____	_____
Genital Ulcer	_____	_____	_____

Which of the following practices do you think are safe or not safe with respect to transmitting STD/HIV?

	Safe	**Possibly Safe**	**Not Safe**
Vaginal intercourse with a condom	_____	_____	_____
Vaginal intercourse without a condom	_____	_____	_____
Oral sex with a condom	_____	_____	_____
Oral sex without a condom	_____	_____	_____
Anal sex with a condom	_____	_____	_____
Anal sex without a condom	_____	_____	_____
Mutual masturbation	_____	_____	_____

Have you ever heard of "Safer Sex"?* ❍ Yes ❍ No

If yes, have you ever practiced "Safer Sex"? ❍ Yes ❍ No

**Safer Sex is any sexual practice that reduces the risk of passing sexually transmitted diseases from one person to another; for example, a mutually faithful relationship between two uninfected partners; the use of a condom for all types of sexual intercourse.*

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SUGGESTED READINGS

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6. Lynch E, Gordon G. Activities to explore: using drama in AIDS and family planning work. London: International Planned Parenthood Federation, 1991.
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TRAINING RESOURCES

Appropriate materials including books for health workers can be obtained from:

1. Soundings, World Neighbours, 4127 NW 122 Street, Oklahoma City, OK 73120
2. TALC, Teaching Aids At Low Cost, Box 49, St. Albans, Herts. AL1 4AX, UK
3. AMREF, African Medical and Research Foundation, Box 30125, Nairobi, Kenya

NEWSLETTERS

There are also a number of newsletters dealing with STD/AIDS, training and PHC issues with up-to-date information, suggestions and articles from many countries. All are free in the developing world and you can receive them regularly for the cost of a stamp.

1. AIDS Action, AHRTAG, 1 London Bridge St. London SE19SG, UK
2. AIDS Health Promotion Exchange, WHO, 1211 Geneva 27, Switzerland
3. Contact, Christian Medical Commission, 150 route de Ferney, 1211 Geneva 2, Switzerland
4. Health Action - Implementing PHC Worldwide, AHRTAG, 1 London Bridge St. London SE19SG, UK
5. Strategies for Hope, Action Aid/AMREF/World in Need, TALC Teaching Aids at Low Cost, Box 49, St. Albans, Herts. AL1 4AX, UK
6. World AIDS, Panos Institute, 9 White Lion Street, London, N19 9PD, UK

CHAPTER 7

STD Drugs

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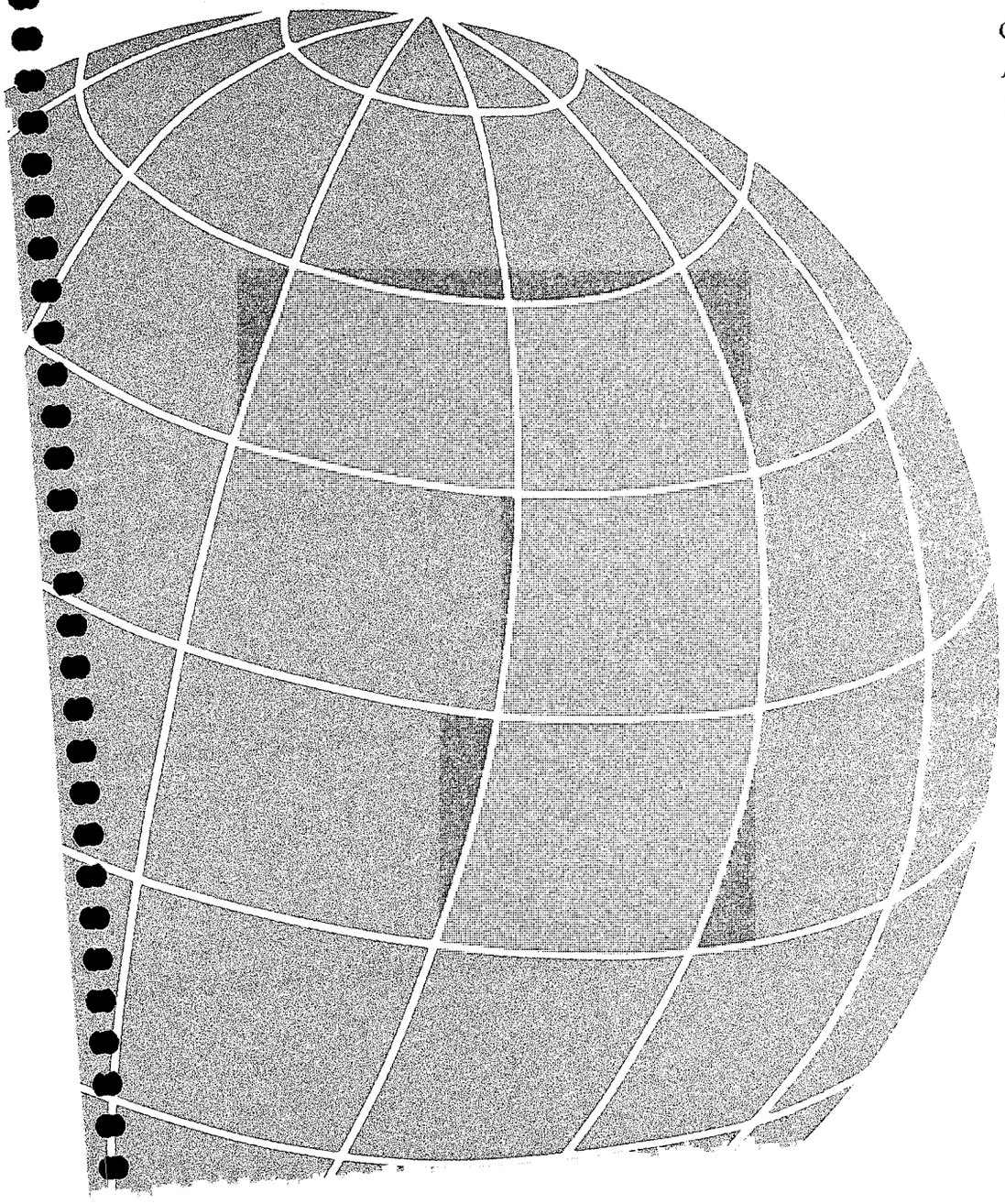


preview CHAPTER 7

STD Drugs

INTRODUCTION

This chapter presents a framework for achieving an adequate level of drug availability, accessibility and affordability for STD treatment by: 1) increasing the efficiency of pharmaceutical services; 2) allocating adequate funding; and 3) implementing user charges and other mechanisms to recover costs.

INCREASING EFFICIENCY

Rational use of drugs is the ultimate goal of national drug policy. One of the first steps is to select the most appropriate drugs. For STDs, drug selection is based on the following criteria:

- High efficacy
- Lowest cost
- Acceptable toxicity
- Microbial resistance that is either unlikely to develop or will be delayed
- Single dosage
- Oral administration
- Not contraindicated for pregnant or lactating women

QUANTIFICATION

Quantifying drug needs is a critical step in the process of supplying drugs for STD treatment and requires the merging of three sets of data:

- A list of drugs used for the treatment of STDs that are registered in the country, with their unit prices
- Average drug quantities required for the treatment of every STD condition
- Epidemiological data (STD prevalence or absolute numbers); strategies for estimating prevalence are described

PROCUREMENT

Procedures for procuring STD drugs are similar to the techniques and rules guiding procurement of other drugs. Low-price procurement may be achieved through the following:

- International open vendors for generic products
- Nonprofit organizations such as UNIPAC, the International Dispensary Association, WHO and the Pan American Health Organization

- Joint drug procurement, another mechanism to achieve a lower price through economies of scale, overhead sharing and higher volumes, has been successfully achieved by Comité Maghrébin d'Achats en Commun in Northern Africa and the Eastern Caribbean Service.

STORAGE

Since antibiotics are very sensitive to light and temperature, proper storage is essential. Poor storage may lead to loss of drug potency. This increases the risk of resistance or even toxicity.

DISTRIBUTION

The majority of drugs used in STD treatment are commonly prescribed for other infections. Health problems posed by STDs are often addressed within the existing framework of primary health-care services rather than through specialized STD clinics. Therefore, the challenge is to ensure that STD drugs are actually used for STDs. STD kits and syndrome selective packaging are useful distribution strategies for ensuring that STD drugs are used primarily for STD infections.

Rational prescribing and strategies for improving adherence to prescribed treatment are other approaches to maximizing the impact of STD drugs.

FUNDING

Funding is usually the most critical factor in the success of STD care and prevention programs. Reconciling budgets and needs is one step in the process. Sensitivity analysis is a technique for doing this. Additional funds can be found through reallocation from other budget line items, from external donors, or by introducing some form of cost-recovery or cost-sharing for use of health services.

RECOVERING COSTS

- Cost-recovery, cost-sharing
- Social marketing

CONCLUSION

Due to the high cost of effective STD drugs, having an adequate supply involves a compromise between therapeutic requirements, financial constraints and the orientation of national drug policies.

INTRODUCTION

Sexually transmitted diseases may rank as the fifth leading cause of morbidity in developing countries.[1] In addition, the presence of an STD, particularly one that produces genital ulcers, increases the risk of HIV transmission.[2] To interrupt the transmission of STD and take advantage of synergism between STD and HIV prevention requires that effective drugs for STD treatment be available, accessible and affordable; and that appropriate information and education be provided to patients.

Unfortunately, the most effective antibiotics, such as quinolones or third generation cephalosporins, are under patent protection and have higher market prices than public health institutions and patients in many developing countries can afford. Therefore, providing drugs for STD treatment is often a compromise between therapeutic requirements and financial constraints. The challenge for many countries is to reach such a compromise in accordance with their national drug policies.

The purpose of this chapter is to provide a framework to guide STD program managers in achieving an adequate level of drug availability, accessibility and affordability for STD treatment. The three key strategies of this framework, as shown in Figure 1, are: 1) increasing the efficiency of pharmaceutical services; 2) allocating adequate funding; and 3) implementing user charges and other mechanisms to recover costs.[3]

INCREASING EFFICIENCY

The ultimate goal of a national drug policy is to ensure the rational use of drugs. This means that the appropriate drugs are prescribed, available at the right time, affordable to those who need them and dispensed correctly. It also means that they are taken in doses as directed at the right intervals and for the necessary length of time.[4] The first step to achieving this goal is to select the most appropriate drugs.

DRUG SELECTION

General criteria

Selection of essential drugs follows well-defined criteria based upon:

- Pattern of prevalent diseases
- The health infrastructure (e.g., types and levels of health institutions)
- Training and experience of health personnel
- Socioeconomic factors
- Characteristics of the drug, which include quality, safety, efficacy, price, availability and cost-benefit ratio[5]

Achieving consensus on the drugs to be used can be relatively easy when treatment is well-established and requires generic products only. Prescribers, dispensers and administrators face a more complex task when additional criteria further complicate the process, as in the treatment of STD.

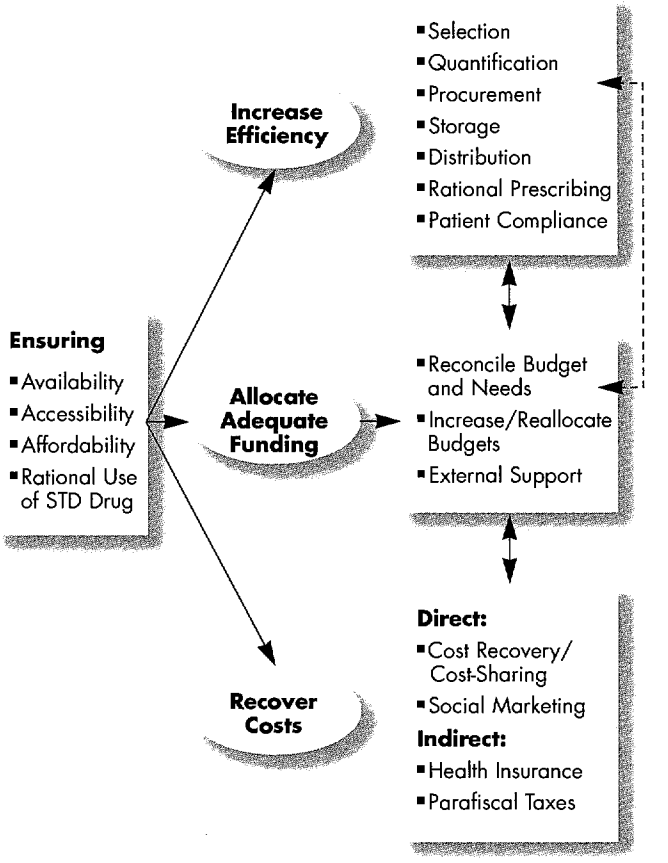
Criteria for STD drugs

At a 1993 meeting organized by the World Health Organization (WHO),[6] members of an advisory group on STD treatments agreed to the following ideal criteria when selecting STD drugs:

- High efficacy
- Lowest cost
- Acceptable toxicity
- Microbial resistance that is either unlikely to develop or will be delayed
- Single dosage
- Oral administration
- Not contraindicated for pregnant or lactating women

(Note: Table 1 lists drugs that can be selected for STD treatment based on these criteria.)

Figure 1
AVAILABILITY, ACCESSIBILITY, AFFORDABILITY OF STD DRUGS
A Framework



Efficacy is the critical factor when choosing among available regimens. Ideally, treatment for STDs should offer at least a 95 percent cure rate. Unfortunately, low-cost antibiotics and chemotherapeutic agents such as tetracycline and penicillin that once provided high cure rates often no longer do so, in part because of illogical therapeutic use and self-medication, which induce the development of drug resistance.

Most resistance to STD drugs has developed in the organisms that cause gonorrhea[7] and chancroid.[8] In *Neisseria gonorrhoeae,* chromosomal resistance involves penicillin and other therapeutic agents (tetracycline,

spectinomycin, erythromycin, thiamphenicol and cephalosporins) and plasmid-mediated resistance affects penicillin and tetracycline. There is growing evidence of decreasing sensitivity of *N. gonorrhoeae* to quinolones in travelers from southeast Asia and from central Africa.[9] *Haemophilus ducreyi,* which causes chancroid, has also developed resistance to antibiotics. Plasmid-mediated resistance has been found against ampicillin, sulfonamide, tetracycline, chloramphenicol and streptomycin. *(For the current WHO recommendations, see Chapter 8.)*

The reasons for the emergence of antibiotic resistance are numerous and complex. They include the practice of self-treatment, repeated episodes of gonorrhea and incomplete use of anti-chlamydial cotherapy in those infected with both gonorrhea and chlamydia.[10] The emergence of new forms of resistance can be unpredictable (e.g., plasmid-mediated tetracycline resistance), and the ease and extent of international travel mean that such problems can spread rapidly.

It is important to identify changes in the local epidemiology of resistant organisms on an ongoing basis. Likewise, selection of STD drugs for individual countries should be based on well-designed epidemiological studies conducted regularly in the populations that frequently use STD services.

For example, in a sample of 50 patients with uncomplicated gonorrhea at the outpatient department of a central hospital, *in vitro* tests demonstrate 42 cases of resistance to co-trimoxazole. Thus, an alternative regimen should be defined using one of the following drugs: ciprofloxacin, ceftriaxone, cefixime, spectinomycin or kanamycin. The choice should be guided by the criteria mentioned above. In many developing countries the treatment cost will be the decisive factor.

Gonococcal infection is prevalent in many areas. The drug chosen to treat syndromes in which gonorrhea is present (e.g., urethral discharge, vaginal discharge and lower abdominal pain) can have a major impact on the total cost. Gonococcal strains worldwide now show high levels of resistance to many common and sometimes newer antibiotics. As a result, WHO recommends quinolones and third generation cephalosporins as first line treatment. Because of cost, often they are not practical and programs frequently choose less expensive alternatives that may be less effective. Clearly, there is a trade-off between increased access to a less effective drug and limited access to a very effective drug. The impact of these alternatives on the population prevalence of STDs is unknown.

Judged on their current usefulness, below is a categorization of STD drugs used to treat gonorrhea (CDC/WHO recommendations).

Universally, no longer useful:

- Penicillins
- Tetracyclines

Useful with varying degress of efficacy:

- Kanamycin
- Spectinomycin
- Ampicillin/clavulinic acid/probenacid
- Trimethoprin/sulphamathoxazole
- Thiamphenicol

Highly effective in most parts of the world:

- 3rd generation cephalosporins (cefixime, ceftriaxone)
- Fluoroquinolones (ciprofloxacin, norfloxacin)*

*(*Note: emerging resistance to fluoroquinolones is being seen in southeast Asia.)*

Choosing more appropriate drugs to respond to drug resistance requires adjustments in procurement procedures: identifying new suppliers, adapting to new purchasing conditions and planning for the impact on lead time (the time interval needed to complete the procurement cycle). In order to avoid shortages because of lack of financial resources, especially at the end of a fiscal year, managers must know the cost implications of changing therapies, evaluate the alternatives and reconcile needs with available budgets.

Table 1

List Of Drugs Used For The Treatment Of STD

[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
acyclovir	tablet	200 mg	Herpes simplex	US$1.746†	ON
azithromycin	capsule	250 mg	Chlamydia	US$3.381†	ON
benzathine benzyl penicillin	vial pd for inj.	1.44 g(2.4 MU)	Syphilis	US$0.398*	OFF
benzene hydrochloride 1% (lindane) 100ml	lotion	1%	Scabies, Pediculosis pubis	US$1.04 IDA	OFF
benzyl penicillin	vial	0.6 g (IMU)	Neurosyphilis	US$0.2208*	OFF
cefixime	tablet	200 mg	Chancroid, Gonococcal infection	US$2.069†	ON
ceftriaxone	IM vial powder for injection	250 mg	Chancroid, Syphilis, Gonococcal infection PID	US$4.338†	ON
ciprofloxacin	tablet	250 mg	Gonococcal infection, Chancroid	US$1.134†	ON
clindamycin	capsule	150 mg	PID	US$0.720†	ON
clotrimazole	vaginal tablet	100 mg	Candidiasis	US$0.0364 IAPS	ON
co-trimoxazole	tablet	400 + 80 mg	Donovanosis, Chancroid, Gonococcal infection	US$0.01264*	OFF
crotamiton 10% 30g	cream	10%	Scabies	US$2.554†	OFF
doxycycline	tablet/capsules	100 mg	Lymphogranuloma venereum, Chlamydia	US$0.0138*	OFF
erythromycin	tablet/capsule	250 mg	Syphilis (pregnancy), Chlamydia, Chancroid	US$0.038*	OFF
gentamycin 2 ml	amp	40 mg/ml	PID	US$0.0958*	OFF
kanamycin	IM vial powder for injection	1g	Gonococcal infection	US$0.3585 IAPS	OFF
metronidazole	tablet	250 mg	*Trichomonas vaginalis*	US$0.072*	OFF
miconazole 30g	gel	25 mg/ml	Candidiasis	US$0.792 ORBI	OFF
norfloxacin	tablet	400 mg	Chancroid	US$0.726†	ON
nystatin	pessary	100,000 IU	Candidiasis vaginal	US$0.055*	OFF
podophyllin 3 ml	solution	0.5%	Genital warts	US$21.917†	OFF
procaine penicillin	vial	1 g (IMU)	Syphilis	US$0.2402*	OFF
spectinomycin	IM vial powder for injection	2 g	Gonococcal infection, Chancroid	US$1.5378 IAPS	ON
tetracycline	tablet	250 mg	Syphilis (allergy), Lymphogranuloma venereum, Gonococcal infection, Chlamydia	US$0.0138*	OFF

° *FOB - Free on Board price is the cost of the drug to the point of placing it on a commercial carrier at the point of origin. It does not include the cost of insurance, packing and shipping.*

* *UNICEF, Supply division - January - June 1995 - Catalog prices in US$ ex-warehouse Copenhagen*

† *British National Formulary. No 27, March 1994. Price originally in UK£. Converted to US$ with exchange rate 1£=US$1.5115*

IAPS - International Association for Procurement and Supply - Rode Kruistraat 22, P.O. Box 37030 - 1033 AA Amsterdam - The Netherlands

IDA - International Dispensary Association - P.O. Box 37098, 1030 AB Amsterdam - The Netherlands

ORBI - Pharma - Van Trierstraat 40, 2018 Antwerp - Belgium

Quantification

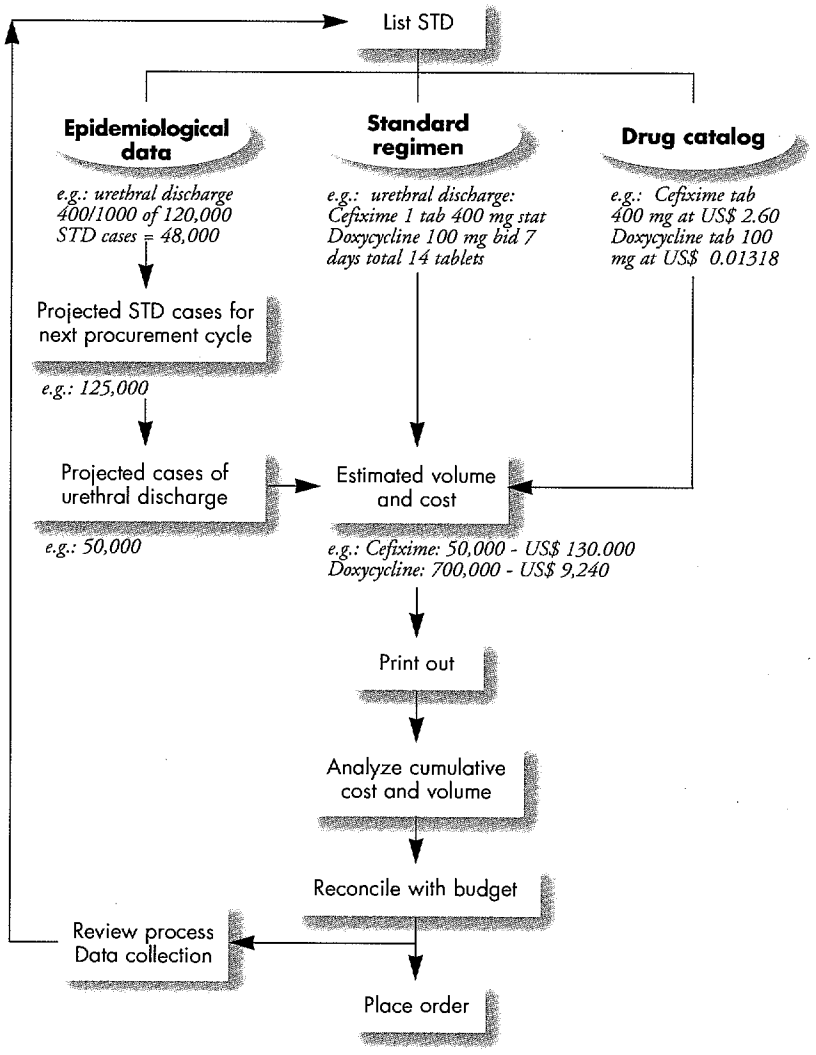
The cost of drugs used for treating STDs is a serious impediment to their procurement in many countries. Acute shortages occur not only because of lack of funding but also because of inappropriate management practices. Managers must be able to quantify their drug needs in order to estimate costs, reconcile financial requirements with available budgets, and plan orders in advance so that unit and freight costs can be minimized. Quantifying needs is therefore a critical step in the process of supplying drugs for STD treatment and requires the input of expert clinicians, pharmacists, administrators and financial officers.

Most drug requirements can be quantified by using either existing data on consumption of the drugs during previous procurement cycles or morbidity data in the population.[1] Unfortunately, drug consumption data are not appropriate for estimating requirements for STD treatment because most of the antibiotics are not used exclusively for STDs. Instead, a method called "the patient morbidity standard treatment method" (PMSTM) is recommended. According to this method, estimated need is obtained by multiplying the expected number of cases of each STD by the total quantity of each drug specified for the corresponding average standard treatment. If a drug is used for more than one STD, the respective totals are added together to obtain the total quantity required.

When done by hand, these calculations can become cumbersome. Computerized spreadsheets or available software specifically designed for that purpose can help.[12]

Three sets of data must be merged to quantify the drugs needed for STD treatment during a time period and to determine their estimated cost: (1) a list of drugs with their unit prices; (2) average drug quantities required for the treatment of every condition (classified either as a syndrome or as a diagnosis); and (3) epidemiological data (prevalence or absolute numbers). These three classes of data are indicated by bolded frames in Figure 2, which shows a simplified algorithm for estimating drug needs.

Figure 2
Algorithm for the Quantification of Drugs Required for the Treatment of STDs



The drug catalog

The drug catalog should list the drugs used for the treatment of STDs that are registered in the country. This list can be easily established by the national Essential Drug Program from the catalog of the Central Medical Store.

The unit price of the drug (the price of 1 tablet or of 1 vial) should be equivalent to the cost insurance and packing (CIP) price to get the unit on the shelf, and not the free on board (FOB) price where the seller bears all the cost up to the point of placing the drug onboard a commercial carrier at the point of the product's origin. In certain countries, the difference between the CIP and the FOB prices can be more than 30 percent.

The standard regimen

The standard regimen lists the average quantities of the drug(s) needed for the treatment of a syndrome or an STD. The practical way of preparing that list is to invite three or four STD experts in the country, a pharmacist with procurement experience and administrators to reach a consensus on drugs and average regimens usually required in adults or children. This consensus ensures the credibility of the quantification and forms the basis for national STD treatment guidelines.

Estimating prevalence of STDs

Collecting data to identify prevalence of STDs is difficult. Morbidity data are usually incomplete, inaccurate or unavailable. Six strategies are proposed to facilitate morbidity assessment. They are not mutually exclusive and it is a good idea to compare and reconcile figures obtained from several sources.

Six ways to assess STD prevalence:

1. *Collect epidemiological data at the national level.*
2. *Collect data from patient records in health institutions.*
3. *Carry out a metanalysis.*
4. *Carry out a prospective sample study.*
5. *Estimate prevalence.*
6. *Project epidemiological data.*

1. *Collecting epidemiological data at national level:*

In most countries, morbidity data recorded in health facilities are consolidated at national or regional levels for epidemiological and planning purposes. Considerable time and effort can be saved if these data can be used to estimate the number of treatment episodes for every STD. When the strategy for management of patients with STDs is based on a syndromic diagnosis *(see Chapter 8),* data may be more reliable since syndromes are more often recorded than specific STD diagnoses established by laboratory tests.

2. *Collecting data from health institutions:*

Health institutions selected for data collection should be representative of the institutions on which people rely for STD treatment. Although specialized STD clinics in urban areas may keep good records, they may be less representative than the private practices of doctors; and they may not represent the situation in rural areas. The lack of laboratory support in nonspecialized peripheral units demands that data be reorganized according to syndromes (e.g., urethral discharge or genital ulcer).

3. *Metanalysis:*

A metanalysis combines the results of independent studies (usually drawn from the published literature) and synthesizes summaries and conclusions that may be used to evaluate prevalence, therapeutic effectiveness and interventions.[13,14] A significant amount of information on STD epidemiology is available and can be used for such a metanalysis.

For example, a literature search on STD epidemiological data in selected countries was carried out on Medline in 1993 using three key words—STD, epidemiology and a country name. As a result, four publications for Thailand, sixteen for Kenya, seven for Zimbabwe and five for Brazil were identified. Each publication quotes prevalence data on STDs and is a good source of information for quantification purposes.

4. *Prospective sample survey:*

If no data are available, then a prospective survey (a survey or study that goes forward in time and follows a group of persons or the records of a group of health facilities) can be carried out to measure STD prevalence. A prospective sample survey can be tailored precisely to meet the data requirements necessary for the calculation. But this requires time and resources.[15]

5. *Estimating prevalence:*

When statistical data are not available and it is not feasible to carry out sample surveys, STD prevalence and reinfection rates can be estimated based on experienced clinical judgments. Among the methods for reaching consensus, the Delphi Approach[16,17] and the nominal group process,[18] which have been widely used in social sciences, can be applied for estimating STD prevalence. Both methods encompass a process to reach a consensus of opinion between members of a panel.

6. *Projecting epidemiological data:*

Whatever method of data collection is used to estimate prevalence, the results will indicate the number of treatment episodes in the past, whereas the desired outcome is to quantify drug requirements for future procurement cycles. If the rate of increase (or decrease) in STD prevalence is known or can be estimated, the estimates of the number of treatment episodes can be adjusted upward (or downward) to allow for expected changes.

The easiest way to make projections of future treatment episodes is to calculate the percentage increase between two previous periods and apply the percentage to the next period, as shown in Figure 3.

Figure 3

A Simple Method to Evaluate Change in Prevalence

Period	STD prevalence or Number of cases	Increase rate (Decrease)
Year n-1	a=2000	
Year n	b=3000	c = b÷a=1.5
Year n+1	d = b x c=4500	

Analyzing cumulative cost

Analyzing cumulative cost is an important step in the quantification process. A drug may account for a significant part of the total recurrent costs because its unit price is very high or because of the quantity needed. Sometimes both unit price and volume are significant.

Usually a small percentage of the total number of drugs ordered during a period of time accounts for a large percentage of total expenditures. Managers need to identify these drugs so they can reconcile estimated costs with their budgets and reach an acceptable compromise between therapeutic needs and financial constraints.

A simple case study *(Appendix 1)* shows how to carry out a cumulative cost analysis. If the analysis shows that a few drugs account for most of the total drug costs, these results can be used to determine whether the drugs are necessary or if they can be replaced with cheaper and just as effective alternatives.

Procurement

Procedures for procuring drugs to treat STDs use the same techniques and rules guiding procurement of other drugs.[19] This section describes different options for procuring drugs, including drugs for STD treatment.

National procurement

Central medical stores, in cooperation with national finance departments, purchase drugs used for STD treatment, following the procurement procedures established in the national drug policy. Low-price procurement, below the United Nations Children's Fund (UNICEF) Supply Division price, is usually achieved through international open tenders for generic products. (A tender is a procedure by which competing bids are made for an advertised or published purchase order.) Prices of branded products under patent protection, which are usually higher, can be negotiated directly with the manufacturer.

Local production

Manufacturing antibiotics requires complex operations and relatively heavy fixed asset investments. Only a few developing countries (like China, India, Thailand) have the level of technology and knowhow to produce antibiotics of good quality at a competitive cost.

Procurement from agency

Several nonprofit organizations such as the UNICEF Packing and Assembly Center (UNIPAC), the International Dispensary Association, the World Health Organization and the Pan American Health Organization procure essential drugs for sale at affordable prices to nonprofit institutions in developing countries. The advantage of using these procurement services are their expertise, low cost and reliability for quality assurance.

Joint drug procurement

Several countries have established joint procurement schemes to reduce procurement costs. Economies of scale, overhead sharing and higher volumes allow lower operational costs and cheaper prices. The Comité Maghrébin d'Achats en Commun in Northern Africa and the Eastern Caribbean Service are examples of successful joint drug procurement.

Whatever the method used, the efficiency of procurement procedures depends heavily on the ability of pharmaceutical services to:

- Plan orders in advance
- Limit the frequency of orders to reduce freight expenditures, and order large volumes to receive low per unit prices
- Monitor use in order to adjust quantities

STORAGE

Drugs for STDs are mostly antibiotics that are very sensitive to light and temperature. Proper storage is of paramount importance. When drugs are stored under especially unfavorable conditions (i.e., inadequate protection from sunlight, moisture and heat), they may lose their potency. This increases the risk of resistance or even toxicity such as in the case of tetracycline.

An STD drug should not be used beyond the expiration date printed on the container, after which time the manufacturer will not guarantee the drug's potency, purity, uniformity or bioavailability (i.e., the rate of the product's absorption from the specific dose form). Loss of potency should never be compensated for by an increase in dosage, because of the serious risk of overdosage and toxicity.

The following tabulation shows storage conditions that should be observed for drugs for STDs:

Table 2

Storage conditions for STD drugs

acyclovir	< 30°	–	Yes	Inactivation
azithromycin	< 25°	–	–	Inactivation
benzathine benzyl penicillin	< 30°	–	Yes	Inactivation Increased sensitivity
benzyl penicillin	< 30°	–	Yes	Inactivation Increased sensitivity
cefixime	< 25°	–	Yes	Inactivation
ceftriaxone	< 30°	–	Yes	Inactivation
ciprofloxacin	< 30°	Yes	Yes	Inactivation
clindamycin	< 25°	–	Yes	Inactivation
clotrimazole	< 20°	Yes	Yes	Inactivation
co-trimoxazole	< 30°	Yes	–	Inactivation
crotamiton	< 30°	Yes	Yes	Inactivation
doxycycline	< 30°	Yes	Yes	Inactivation
erythromycin	< 25°	–	Yes	Inactivation
gentamycin	< 25°	–	Yes	Inactivation
kanamycin	< 30°	–	Yes	Inactivation
metronidazole	< 30°	Yes	–	Inactivation
miconazole	< 30°	Yes	–	Inactivation
norfloxacin	< 30°	Yes	Yes	Inactivation
nystatin	2° T° 8°	Yes	–	Inactivation
podophyllin	< 25°	Yes	Yes	Inactivation
procaine penicillin	< 30°	–	Yes	Inactivation Increased sensitivity
spectinomycin	< 30°	–	–	Inactivation
tetracycline	< 30°	Yes	–	Toxicity Inactivation

Source: Martindale, the extra pharmacopoeia. 30th edition, London, 1994, The Pharmaceutical Press.

Distribution

Distribution, the process of moving STD drugs from a central point (e.g., a central medical store) to an STD patient, involves administrative procedures as well as transport, storage and user facilities.

The majority of drugs used in STD treatment are also commonly prescribed to treat other infections. Antibiotics, an expensive and scarce commodity in developing countries, are in great demand. If antibiotics for STD were indiscriminately distributed to peripheral health institutions, there would be no possibility of limiting their use to STD infections, because of a chronic shortage and ethical considerations.

Therefore, the challenge is to ensure that drugs for STDs are actually used for that purpose. This can be achieved by a verticalization of STD services through which activities are carried out by a trained staff in specific STD prevention and care, and STD drugs are exclusively distributed.

However, verticalization is not compatible with the structure of health care services in most cases. Health centers in developing countries satisfy the demand of 80 to 90 percent of the population living in rural and periurban areas. It is estimated that 10 percent or more of their daily workload may be related to STD and their complications.[20]

Therefore, health problems posed by sexually transmitted infections must be addressed within the framework of existing primary health care services rather than through the establishment of specialized STD clinics. Although these STD clinics may be effective, they are usually expensive and reach only small segments of the population. Two distribution strategies may solve this dilemma.

Distribution strategies

a. *STD kits:*

Kits are sealed containers with standard volumes of a designated range of medical supplies for dispatch to peripheral health units. Their use requires accurate estimate of quantities required for all sectors and appropriate selection of drugs. Drug kits have the advantage of controlling pilferage, reducing waste and facilitating distribution. On the other hand, they introduce some rigidity into the system, which may not allow adequate response when demand for drugs used to treat STDs at peripheral level is fluctuating between procurement cycles. Kits for STD drugs could be an effective method of supplying units through the usual distribution channels and of promoting integration of STD prevention into the existing health care delivery system.

b. *Syndrome selective packaging:*

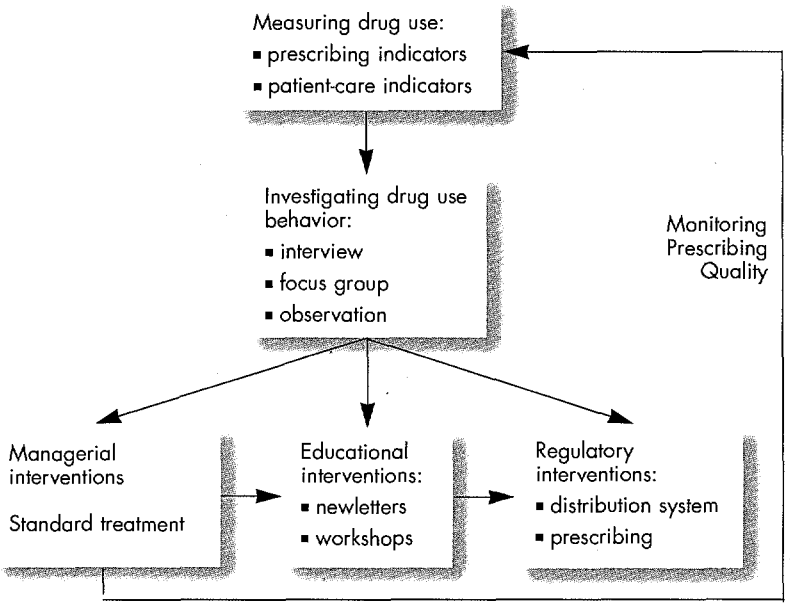
Like STD drug kits, syndrome selective packaging (SSP) provides a package of standardized STD treatment. But SSP targets the ultimate user—the patient. SSP kits are sealed packs containing the full treatment course for a syndrome. For example, an SSP kit for genital ulcer might contain 20 condoms, an injection of 2.4 MU of benzathine penicillin to be administered by a health worker, one tablet of ciprofloxacin, an instruction leaflet and a partner referral card. Although packing them may prove relatively expensive, SSP kits are worth considering, particularly for social marketing of STD drugs. SSP kits require that personnel responsible for their distribution be adequately trained in their use and also in patient counseling.

Rational Prescribing

Antibiotics, popular drugs among patients and prescribers, are often used inadequately. A study carried out by WHO in three African countries revealed that 27.3 percent of ambulatory patients and 51.7 percent of hospitalized patients received antibiotics; more than 30 percent of these prescriptions used injectable forms, and there was a lack of proper clinical examination and diagnosis. [21]

Prescribing is a very complex process in which the prescriber is influenced by the following: the disease (severity); the patient (age, sex, sociocultural factors); the prescriber's access to drug information, his or her working conditions (diagnostic, facilities, referral system, income) and professional skills; and the level of the availability and accessibility of drugs determined by the national drug policy. [22]

Figure 4
HOW TO IMPROVE PRESCRIBING PRACTICE



There are several techniques to evaluate STD drug use practices and assess the influence of these factors: in-depth interviews (prescribers and patients), focus group discussions, observations and the use of surrogate patients. Based on the result of studies using these techniques, managerial, educational or regulatory interventions can be implemented.[23] Figure 4 shows a process to improve prescribing practices.

PATIENT COMPLIANCE

Lack of adherence to treatment is a universal problem. A study in Canada showed that 37 percent of TB patients were non-compliant with anti-TB drugs.[24] Factors contributing to adherence encompass communication between doctor and patient (on treatment rationale, disease, drug efficacy, adverse reactions), suitability of drugs, physician error and drug efficacy.[25] There are several patterns of patients who request medical advice but do not follow it:

- Those who are motivated but lack knowledge
- Those who are knowledgeable but insufficiently motivated
- Those who are unable to adhere to treatment because of external constraints
- Those who decide against the recommendations

Patient adherence to treatment and the prescribing behaviors of health care providers are linked. They should always be examined together as part of quality of care assessment. It is difficult to improve adherence to treatment because of the intricacy of the above factors and the variety of situations. The bottom line however is very simple: doctors must communicate better with their patients before asking them to better adhere to treatment *(see Chapter 10)*. The strategy for improving adherence includes prescriber education, patient counseling, regimen simplification and, if possible, a constant adherence monitoring.

ALLOCATING ADEQUATE FUNDING

Funding is a critical (if not the most critical) factor in the success of STD care and prevention programs. For instance, treatment cost of one episode of urethral discharge would reach around US$ 2.7 with the use of cefixime 400 mg in a single dose and doxycycline 100 mg twice daily for seven days. In comparison, the average public drug expenditure per capita per year does not exceed one dollar in many African countries.

Reconciling Budgets and Needs

As indicated earlier, reconciling budgets and needs is one of the steps of the quantification process. In a calculation of drug cost, some items have a greater influence on the final result than others. It is useful to identify these items so they can be subjected to special scrutiny, such as therapeutic rationale, pertinence, existence of less expensive alternatives, etc.

Techniques for doing this are called sensitivity analysis. To identify the drugs that are most costly, doing a cumulative cost analysis is recommended as shown in Appendix 1. If budgets cannot be increased, cheaper alternatives can be chosen, regimens can be changed and cheaper sources of procurement can be identified.

Increasing, Reallocating Budgets; Seeking External Support

When needs exceed the available budget, it may be possible to increase funding or to reallocate funds from one budget line to another. However, many developing countries have found it difficult to meet recurrent health costs from their own budgets because of the status of their national economies and other budget priorities for development or defense. Donor support is another option for increasing funding for STD drugs. However, donors are reluctant to support recurrent costs, particularly for drugs, because of the risk of diversion and therefore of uncontrollable inflation of expenditure.[26] The following standards for project design should reduce donor apprehension:

- Select small-scale projects
- Always incorporate monitoring
- Give high visibility to the project
- Ensure appropriate technical support
- Integrate the project within existing systems
- Incorporate self-financing schemes for sustainability in the longterm

Recovering Costs

Another approach to matching funds with needs is to introduce innovative funding mechanisms in which patients are directly or indirectly charged for the services they receive from health care institutions.

Direct User Charges

Cost-recovery, cost-sharing

Many developing countries have implemented user charges for health services as a way to generate financial support to the health sector.[27] Payment at time of illness can be based on cost-recovery (when the patient pays the total cost of the service, including consultation fees and drugs) or on cost-sharing (when the patient pays a fraction of the cost). Payment can be made for each visit to a health institution, per episode of illness or for consultation and/or drugs separately.

When designing user charges, it is important to consider the impact on equity and efficiency. If poverty-stricken people are more price-sensitive than those who have more money, then user charges would reduce the use of STD services by the former. Implementing user charges only for STD drugs in the public sector would also single out STD treatment procedures and patients. Not only might this be unacceptable to patients, it also might induce discrimination against people suffering from STDs and HIV/AIDS.

The effectiveness of user charges depends on people's willingness and ability to pay. Perceived quality of service is one of the most important determinants of people's willingness to pay, and experience has shown that cost-recovery schemes may have a negative impact on health status if not carefully designed and implemented.[28,29]

Social marketing

The use of commercial marketing techniques to address social or public health problems is another way of recovering some or all of the cost of STD drugs.[30] It is also an attractive way to increase the acceptability and accessibility of STD prevention and treatment for target groups.

Social marketing requires thorough market research, promotion, and sale of services and products (usually at subsidized prices) at locations and times that are convenient for the target audience. Only a fraction of the infected population (especially among women) seeks appropriate treatment for an STD from an accredited source for a variety of reasons, including social and cultural perceptions of STD and lack of access to efficient, high-quality services. Thus, social marketing should be an attractive way to increase the acceptability and accessibility of STD prevention and treatment for target groups, especially for those who do not seek treatment.

Social marketing has been widely used in condom distribution.[31] Using this approach for other aspects of STD prevention is more complex because it entails a mix of tangible (drug therapy) and intangible products (diagnosis, education, partner referral). Dissociating certain components of this product mix—such as selling drugs without training prescribers in syndromic diagnosis, and without educating patients about treatment compliance and partner referral—could result in irrational use, wastage and drug resistance.

Therefore, social marketing should focus not only on drugs but, more comprehensively, on the control of STDs. Social marketing of drugs for the treatment of STDs is likely to be difficult to implement. However, experience in other domains shows that because of its positive impact on sustainability and self-sufficiency, it is an avenue worth exploring.[32] This approach was piloted in Cameroon under the name of *Mstop* *(see Chapter 13 for full discussion).*

Long-term sustainability of direct user charges depends on foreign currency availability. It is necessary for revenues raised in local currency to be converted into foreign currency to procure either finished products or raw material on the international market.

Indirect User Charges

Indirect financing mechanisms for drug purchase are usually derived from taxes, mutual funds or insurance schemes. These mechanisms are difficult to extend to unemployed people who constitute the majority of the population in many countries, and are not easy to implement in view of their social, administrative and economic implications.[33]

CONCLUSION

Common STDs represent a significant burden in many societies and rank among the top ten most important health problems in developing countries. Their prevention requires that effective drugs be available at all times and that adequate information and education be provided to patients. Because of the high prices of effective drugs, the supply of drugs for the treatment of STDs requires a compromise between therapeutic requirements, financial constraints and the orientation of national drug policies.

The three key components of a strategy to ensure adequate supply are increasing efficiency in pharmaceutical services, allocating adequate funding after a careful estimate of needs, and implementing user charges and other cost-recovery mechanisms. Innovative distribution strategies or mechanisms, such as social marketing, have to be carefully designed in order to gain acceptance and minimize the risk of encouraging further development of drug resistance.

APPENDIX 1

QUANTIFICATION: A CASE STUDY

A. In an African country of 7 million inhabitants, it is estimated that 355,000 STD cases (with the distribution below) will be treated in the public sector during the next procurement period.

Genital ulcer	46%
Urethral discharge	24%
Vaginal discharge	30%

The following regimens were chosen:

Vaginal discharge	clotrimazole 200 mg 1pessary bid for 3 days
	metronidazole 250 mg 1 tab. bid for 7 days
	doxycycline 100 mg 1 tab. bid for 7 days
Urethral discharge	cefixime 400 mg 1 tab. stat
	doxycycline 100 mg 1 tab. bid for 7 days
Genital ulcer	benzathine benzyl penicillin 2.4 MU IM stat or doxycycline 100 mg 1 tab. bid for 15 days in case of allergy (10% of cases)
	erythromycin 250mg 2 tab. tid for 7 days

B. The quantification of needs gives the following results:

Drug	Cost (US$)	Cumulative cost (US$)	Cumulative Percentage of Cost
cefixime tab 400 mg	213,000	213,000	63%
benzathine benzylpenicillin 2.44 MU vial (1440 mg)	59,640	272,640	80%
doxycycline tab 100 mg	42,947	315,587	93%
clotrimazole pes. 200 mg	22,365	337,952	100%

The total cost of STD cases is estimated to be around US$ 338,000, almost 1 dollar per case. Cumulative cost shows that cefixime alone accounts for 63 percent of the total drug cost for STD (US$ 213,000).

continued next page

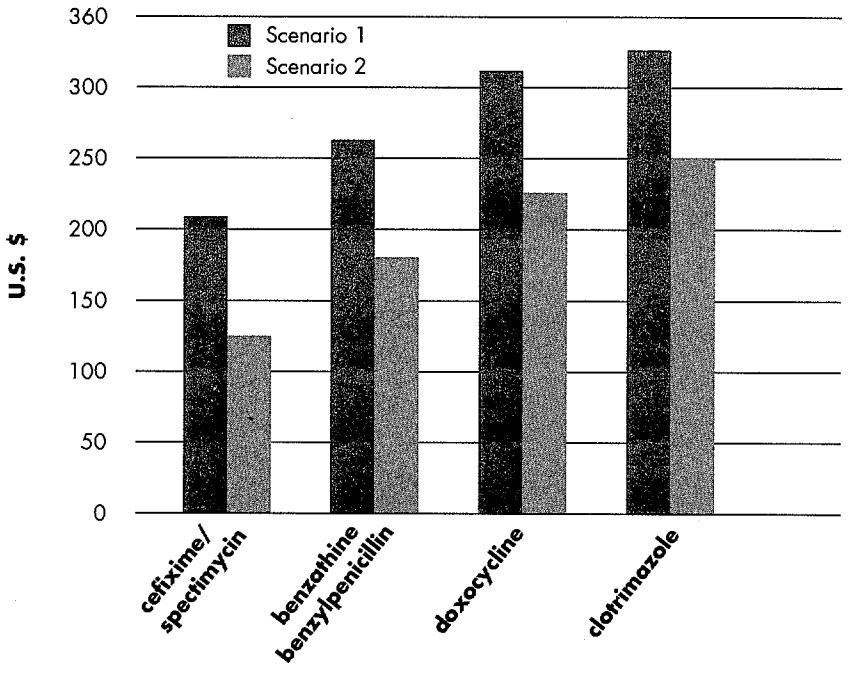
C. A sensitivity analysis is made to see what happens if one replaces cefixime with spectinomycin (scenario 2).

Drug	Cost (US$)	Cumulative cost (US$)	Cumulative Percentage of Cost
spectinomycin vial 2 g	131,208	131,208	51%
benzathine benzylpenicillin 2.44 MU vial (1440 mg)	59,640	190,848	74%
doxycycline tab 100 mg	42,947	233,795	91%
clotrimazole pes. 200 mg	22,365	256,160	100%

In this case, the total cost decreases by about US$ 80,000, spectinomycin alone accounting for 51% of the total cost.

Sensitivity Analysis: Cumulative Costs

D. Based on this finding, and after careful consideration of in vitro-resistance of spectinomycin, it was decided to change the regimens by replacing cefixime with spectinomycin. The total estimated drug cost was reduced by more than 30 percent.



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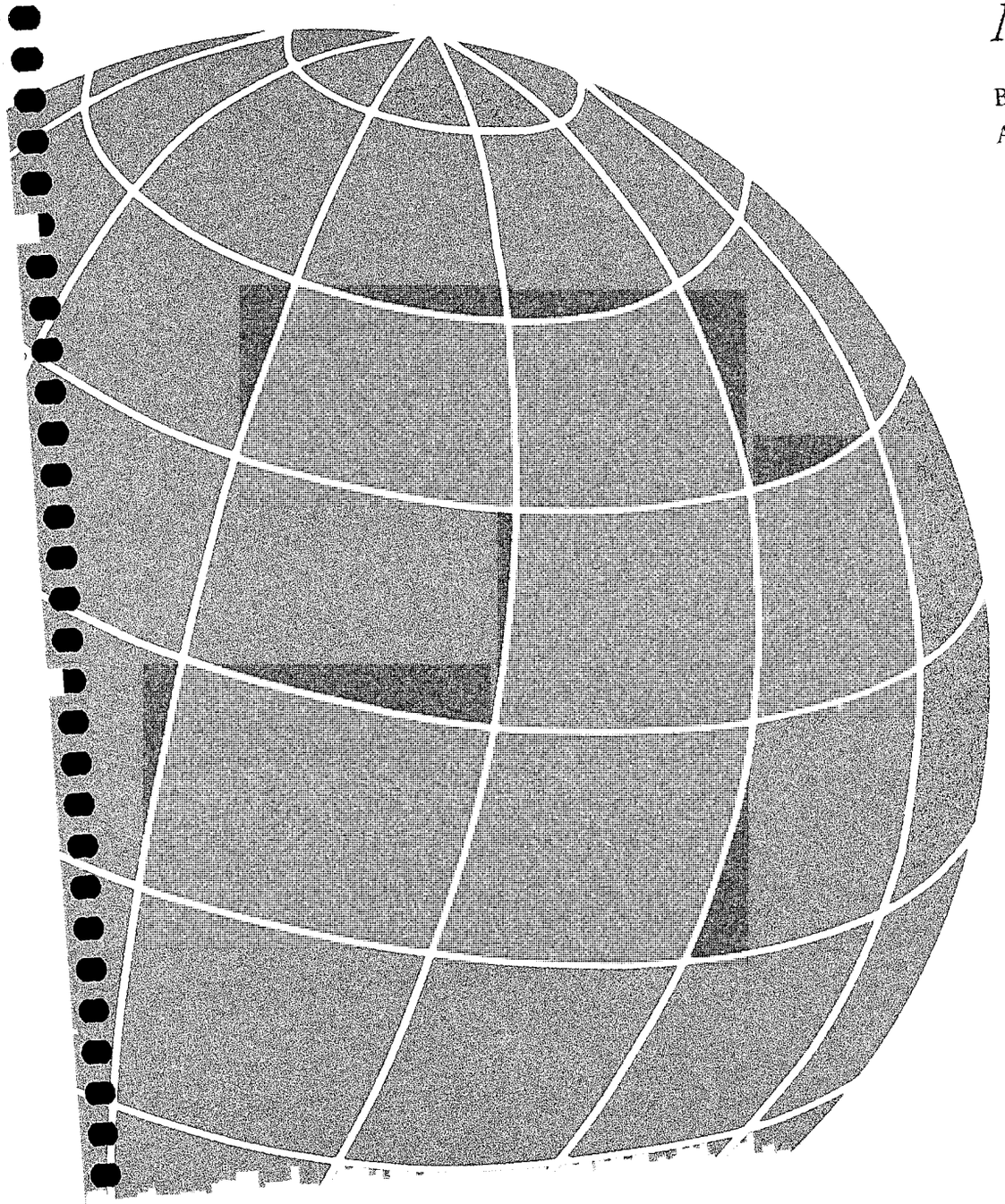
CHAPTER 8

STD Syndrome Management

BEA VUYLSTEKE
ANDRÉ MEHEUS



preview CHAPTER 8

STD Syndrome Management

INTRODUCTION

The essence of STD control is comprehensive case management. Patients receive immediate health benefits from prompt and effective detection and treatment. In addition, the population benefits from decreased STD incidence and prevalence due to a reduction in the duration of patient infectiousness.

THE SYNDROMIC APPROACH

The syndromic approach to STD case management involves the detection of a syndrome—symptoms and signs associated with a number of well-defined etiological agents. It relies on the use of a clinical flowchart—a step-by-step standardized guide to medical decision making. Once a syndrome has been identified, treatment can be provided for the majority of the organisms responsible for that syndrome. The syndromic approach is well suited to resource-poor settings and enables health-care workers to make a diagnosis within a short time without special skills and sophisticated laboratory tests.

DESIGN OF FLOWCHARTS

A team of public health specialists should design diagnostic and therapeutic flowcharts for use at the national level. Background information on local etiologies of STD syndromes, including mixed etiologies, is essential. Data on validity and cost-effectiveness can be obtained from the literature or from special studies described in detail here. Decisions on cost-effective treatments must be based on local or regional antimicrobial susceptibility patterns, results of treatment trials, toxicity data and drug cost.

Feasibility should always be assessed before a flowchart is introduced. Such an assessment should determine whether a flowchart is operational, acceptable to provider and patient, and adaptable.

MOST COMMON STD SYNDROMES AND FLOWCHARTS

Flowcharts in use that manage the most common STD syndromes include the following:

- Urethral discharge syndrome in men
- Epididymitis: a complication of untreated urethral syndrome
- Lower genital tract syndrome (LGTS)
- Pelvic inflammatory disease (PID): a complication of untreated endocervicitis
- Genital ulcer syndrome (GUS)

CONCLUSION

Syndromic diagnosis and treatment is perfectly adapted to primary health-care settings because it is simple, rapid and does not depend on elaborate laboratory tests. By using clinical flowcharts, syndromic guidelines can be implemented in a standardized way on a large scale.

Local data on etiology and antimicrobial susceptibility are necessary in designing an effective flowchart, and there is no one flowchart that is universally applicable. Every flowchart represents a compromise between diagnostic accuracy and technical and financial realities.

A syndromic approach for managing patients with STDs is currently in use in many developing countries, resulting in well accepted, quality STD care in primary health-care settings.

INTRODUCTION

Comprehensive case management of STDs is the cornerstone of STD control. Prompt and effective case detection and treatment result in immediate health benefits for individual patients. Furthermore, reducing the duration of patients' infectiousness decreases the incidence and prevalence of STDs in the population. Curative services for STDs offer unique opportunities for health education, including the promotion of condom use for those at greatest risk of acquiring STDs and HIV infection. Finally, it is possible to detect and treat asymptomatic STDs by identifying the contacts of STD patients *(see Chapter 11).*

CASE MANAGEMENT IN DEVELOPING COUNTRIES

Developing-country health providers at all levels, in both the public and private sectors, are likely to be confronted with many patients with STDs. In some developing countries, STD-related complaints are among the most common reasons why adults seek health care.[1]

Primary health care facilities in developing countries and other resource-poor settings face several constraints to the optimal management of patients with STDs. These constraints include:

- Lack of access to the laboratory technology necessary for making etiologic diagnoses of STDs
- Shortages of well-trained staff
- High workloads and limited staff time available per patient

THE SYNDROMIC APPROACH

In resource-poor settings the appropriate diagnostic tool should enable health care workers to make a correct diagnosis in most patients:

- Without sophisticated laboratory tests
- Without specialized skills
- Within a short time, and preferably without the need for a repeat visit by the patient

The **syndromic approach** allows health care workers to make a diagnosis without sophisticated laboratory tests. This approach is based on identifying a syndrome—a group of symptoms and easily recognized signs associated with a number of well-defined etiologies. Once a syndrome has been identified, treatment can be provided for the majority of the organisms responsible for that syndrome.

Several STD syndromes can be managed easily and rapidly using clinical **flowcharts** for diagnosis and treatment. A clinical flowchart (also known as an algorithm or decision tree) pictures a path of diagnostic reasoning. It is a logical, step-by-step, standardized guide to medical decision making. The World Health Organization (WHO) recommends that national STD control programs incorporate diagnostic and therapeutic flowcharts into their STD management guidelines.[2]

ADVANTAGES OF FLOWCHARTS

STANDARDIZATION

Flowcharts rationalize and standardize clinical decision making. Their use also can standardize diagnosis, treatment and referral. Such standardization:

- Makes STD reports from different health facilities comparable
- Simplifies STD data collection and analysis, which in turn facilitates surveillance and planning (e.g., the purchase of drugs and other supplies)
- Facilitates supervision of health care workers because the approach is the same in every health facility
- Ensures that STD patients receive the same treatment for a given condition in every health facility, enhancing confidence in health services
- Delays the development of antimicrobial resistance of sexually transmitted microorganisms

Training Tool

Training must reflect reality and be problem-oriented. Flowcharts are useful training tools because they are based on the presenting symptoms and show the path of diagnostic reasoning to reach a proper diagnosis and to prescribe the best treatment.[3] The skills of history taking and physical examination must not be neglected in this approach. Health care workers should learn to ask the most relevant questions, including questions on sexual behavior, and to look for the most important physical signs *(see chapter 6)*. Active participation of students in the logical, step-by-step construction of flowcharts is educationally beneficial and facilitates their acceptance and use.

Design of Flowcharts

A team of public health specialists should design diagnostic and therapeutic flowcharts for use at the national level. Key people to involve in the design include the coordinators of national programs, including STD/AIDS control, primary health care, essential drug, family planning, and maternal and child health. In some situations it is advisable to ask specialists such as gynecologists, microbiologists, genito-urinary specialists and pharmacists to participate. The involvement of these specialists can help ensure their cooperation and increase the acceptance of the flowcharts.

To ensure that as many patients as possible receive correct diagnoses, background information on local etiologies of STD syndromes, including mixed etiologies, is essential in designing an STD management flowchart. Data on validity and cost-effectiveness can be obtained from the literature or from special studies *(see below)*. Decisions on the most cost-effective treatments must be based on local or regional antimicrobial susceptibility patterns, results of treatment trials, toxicity data and the cost of the drugs.

To ensure efficient management of STDs, flowcharts should be adapted to the level of development of the health services. Feasibility is determined by:

- The presence of laboratory facilities
- The infrastructure available for physical examination (availability of an examination room with privacy, examination table, adequate specula, gloves and light source, and facilities to disinfect specula regularly)
- The level of training of personnel (e.g., are they able to perform a speculum examination?)
- Access to a higher-level health care facility
- The drugs available in health care facilities
- The staff time available per patient

Local and cultural perceptions about STDs and health-seeking behavior will to a large extent determine the usefulness of certain flowcharts. For example, when designing a flowchart one should consider whether a genital examination by a health care worker of the opposite sex is culturally acceptable.

Evaluation and Validation of Flowcharts

The three parameters to be assessed in the evaluation of flowcharts are:

1. Validity
2. Cost-effectiveness
3. Feasibility

Validity: sensitivity and specificity

Sensitivity and specificity are assessed by comparing the outcome of a diagnosis made with the flowchart with a gold standard diagnosis.

Calculating the sensitivity and specificity of a flowchart

	Gold Standard		
	+	-	Total
Flowchart +	A (true +)	B (false +)	A + B
Flowchart -	C (false -)	D (true -)	C + D
Total	A + C	B + D	A+B+C+D

The sensitivity of the flowchart is defined as the proportion of infections detected by the flowchart (A/A+C). The specificity is the proportion of patients without infection who are correctly identified by the flowchart (D/B+D). The positive predictive value (PPV) of the flowchart represents the proportion of diagnoses confirmed by a gold standard laboratory diagnosis (A/A+B). The negative predictive value (NPV) represents the proportion of negative results confirmed by laboratory diagnosis (D/C+D; *see example, Box 1*).

When all patients presenting with a symptom (such as urethral discharge) are treated syndromically, all boxes in the row "flowchart-" becomes 0, and the sensitivity is always 100 percent, while the specificity is indeterminate. In that case, it is more important to assess the positive predictive value of the flowchart for different etiologies.

Sample size

To determine the sample size needed to test the validity of a flowchart, a sample size calculation for a binomial proportion is used as described below. The sample size (N) will depend on the:

- Z score, which is 1.96 for the confidence level 95%
- Expected sensitivity of the flowchart: p (one may also use the expected specificity or positive predictive value)
- Desired precision of this expected proportion: L
- Prevalence of the STD in the group to which the flowchart will be applied

Box 1:

Calculating the Sensitivity and Specificity of a Flowchart

Of 255 women who presented with vaginal discharge at a primary health care center, 85 were diagnosed with cervicitis, based on symptoms and the clinical sign of endocervical mucopus. At the same time, samples were taken to perform the gold standard analysis, which consisted of culture for *Neisseria gonorrhoeae* and enzyme-linked immunosorbent assay (ELISA) for chlamydial infection. After adding the results of the gold standard diagnosis, we can calculate the following:

	Cervicitis by GC Culture & Chlamydia ELISA		
	+	-	Total
Flowchart+	15	70	85
Flowchart-	30	140	170
Total	45	210	255

Prevalence of gonococcal or/and chlamydial cervicitis in this population: 45/255 = 17.6%

Validity of the algorithm:

sensitivity: 15/45 = 33.3%
specificity: 140/210 = 66.6%
PPV: 15/85 = 17.6%
NPV: 140/170 = 82.3%

The formula for sample size is:

$$N = \frac{(1.96)^2 \times p \times (1 - p)}{L^2}$$

Example: We want to assess the sensitivity of a flowchart on vaginal discharge for the diagnosis of gonococcal and/or chlamydial cervicitis. We expect a sensitivity of 70 percent and want a precision of 10 percent (range of sensitivity from 60 to 80 percent). The number of infections needed to test the validity of a flowchart will be:

$$N = \frac{(1.96)^2 \times 0.70 \times 0.30}{0.10^2}$$

N = 80.7, OR 81 INFECTIONS.

Therefore, if the prevalence of gonococcal and/or chlamydial infections in a population of women with vaginal discharge is, say, 25 percent, the sample size will be 81/0.25 = 324 symptomatic women.

Practical issues

The study population for validity testing has to be as representative as possible of the population in which a flowchart will be used. As long as enough STD patients are consulting to reach the necessary sample size within a reasonable time and a reference laboratory is available for the gold standard tests, a primary health care setting is suitable. In general, sophisticated laboratory tests are needed for gold standard diagnosis. If some patients consulting at the primary health care level have already taken drugs, it is important not to exclude them from the validity study.

When testing the validity of flowcharts, it is preferable to have two examination rooms. In one room, a health care worker can follow the directives of the flowchart and make a therapeutic decision. Then the patient can be asked to enter a second room, where a more systematic examination can be done and where specimens will be taken for the gold standard laboratory tests. Because a speculum examination is sometimes not included in STD flowcharts, using such a setting will ensure that the therapeutic decision is not based on the findings of the speculum examination.

The likely outcomes of diagnoses made using a flowchart can be simulated retrospectively, using data from history taking, physical examination and laboratory tests. This desk exercise can be very useful for evaluating modifications to flowcharts without repeating studies. For example, it could be used to assess what would happen to the specificity of a flowchart if the gram stain examination were omitted.

Interpretation of the sensitivity and specificity of a diagnostic flowchart

Example for gonococcal and/or chlamydial cervicitis

	Gold Standard *N. gonorrhoeae/C. trachomatis*		
	+	-	**Total**
Flowchart +	correctly treated	over treated	number of women treated
Flowchart -	missed cases	correctly diagnosed as negative	number of women not treated
Total	*N. gonorrhoeae* + or *C. trachomatis* +	*N. gonorrhoeae* - and *C. trachomatis* -	number of women tested

A low sensitivity of the symptoms/signs implies that only a small proportion of the gonococcal and/or chlamydial infections will be detected with the flowchart, which relies only on symptoms and signs for treatment decisions. Missed cases place the infected person at continued risk of more serious complications and result in further disease dissemination.[1]

A low specificity means that many negative cases are wrongly considered positive. This results in over treatment, leading to:

- Unnecessary side effects, drug costs and partner notification
- The psychological cost of inappropriate labeling

Do all flowcharts need to be validated in all countries?

Most flowcharts for urethral discharge and genital ulcers have been shown to be sufficiently valid in different settings that they can be used widely without repeating a validity test. The validity of a hierarchical flowchart starting with the symptom vaginal discharge is under discussion. In a few countries, WHO and AIDSCAP are testing and comparing the classical flowchart for vaginal discharge and a flowchart based on a risk score. Other countries from the same regions can rely on these results to guide them in developing their own national flowcharts.

Cost-effectiveness

The cost-effectiveness of a flowchart can be calculated in many different ways. It is not within the scope of this chapter to describe in detail the methodology of cost calculation. Only the cost per patient will be discussed comprehensively, with general comments on the cost per case cured and long-term costs. A relative estimate of these costs can be made without sophisticated calculation based on the positive predictive value (PPV), treatment efficiency and sensitivity.

Cost/patient

The cost per patient C is the cost incurred by the health structure in applying a flowchart to one patient. It is the sum of all the costs of diagnosis and treatment divided by the total number of patients for whom the flowchart is used.

Or:

$$C = (P_d \times \text{DIAGNOSIS}) + (P_t \times \text{TREATMENT})$$

Wherein P is a proportion, P_d is the proportion of patients who will undergo diagnosis (examinations, tests) and P_t is the proportion of patients who will be treated.

Example

Take, as a consideration, 200 men attending a health center to seek treatment for urethral discharge. On clinical examination, 180 of these men had urethral discharge. Of the 180 men with urethral discharge, 140 had a positive Gram stain.

According to flowchart A (not shown), treatment for gonorrhea and chlamydial infection is given to all patients with clinically confirmed urethral discharge. According to flowchart B (not shown), a Gram stain is performed. If intracellular gram-negative diplococci (IGND) are seen on Gram stain, treatment will be given for both infections. If no IGND are seen, the patient will be treated only for chlamydial infection. We want to know which of the two flowcharts is the cheapest.

The prices used in this exercise were: U.S. $0.10 for a physical examination (gloves, disinfectant), U.S. $0.30 for a Gram stain, U.S. $0.50 for Chlamydia infection treatment (doxycycline, seven days) and U.S. $2.50 for a treatment for gonorrhea (norfloxacin, one dose).

The cost per patient applying flowchart A would be:

$$C = (200/200 \times \text{U.S.\$0.10}) + (180/200 \times \text{U.S.\$3.00}) = \text{U.S.\$2.80}$$

The cost per patient applying flowchart B would be:

$$C = (200/200 \times \text{U.S.\$0.10}) + (180/200 \times \text{U.S.\$0.30}) + (140/200 \times \text{U.S.\$3.00}) + (40/200 \times \text{U.S.\$0.50}) = \text{U.S.\$2.57}$$

Figure 1
MANAGEMENT OF URETHRAL DISCHARGE

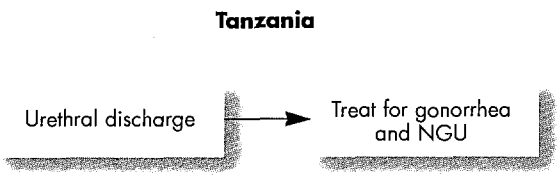
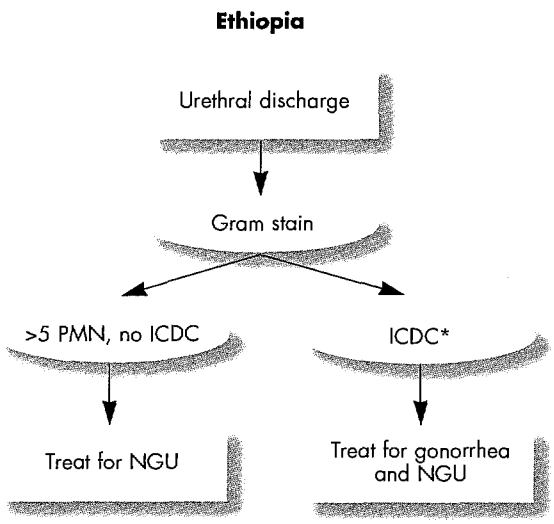


Figure 2
MANAGEMENT OF URETHRAL DISCHARGE



* *Intracellular diplococci*

Cost/case cured

The cost per case cured is the cost per case completely cured when a flowchart is applied to every patient. It is the sum of all costs of diagnosis and treatment divided by the number of cases diagnosed, treated and cured. If a patient had more than one infection, every infection successfully treated is considered one case cured.

The cost per case cured will be determined by the PPV of the flowchart: the higher the PPV, the lower the cost per case cured. The PPV itself is determined by the prevalence of that STD and the specificity of the flowchart.

Long-term costs

Long-term costs will be determined in part by the cost of complications and sequelae, such as urethral stricture, chronic pain, extra-uterine pregnancies and infertility. These complications can be minimized by prompt and effective treatment. If a flowchart has a low sensitivity, missed or incorrectly treated infections will result. Treatment failure is also associated with the resistance pattern of the antibiotic used. Thus the higher the sensitivity of the flowchart and the more effective the treatment, the lower the long-term costs will be. A balance must be reached between immediate costs and long-term costs.

Long-term costs also depend on days lost from work by STD patients and the number of additional people infected by someone with an STD, including secondary HIV infections. These long-term costs are very difficult to estimate.

Feasibility testing

Feasibility should always be assessed before a flowchart is introduced. Such an assessment should determine whether a flowchart is:

- **Operational:** does a given health care facility or group of facilities have the material and skills to implement it?

- **Acceptable:** will the method be accepted by health care workers and will STD patients comply with diagnosis and treatment?
- **Adaptable:** can the method be adapted to different settings and changing circumstances?

Questions about whether a flowchart is operational and acceptable can be answered by analyzing available information. Acceptability and adaptability can be tested quickly in small-scale pilot studies. Patient acceptability can be assessed through "exit interviews" with patients as they leave the clinic, and health care workers can be interviewed before and after using the flowchart. Interviews and observations of health care workers are important tools for assessing the practicality as well as the acceptability of the flowchart.

MOST COMMON STD SYNDROMES AND FLOWCHARTS

This section presents flowcharts currently in use to illustrate some of the different options for managing the most common STD syndromes.

URETHRAL DISCHARGE SYNDROME IN MEN

Common Symptoms	Common Clinical Signs	Most Common Causes (etiology)
▪ urethral discharge	▪ urethral discharge	▪ gonorrhea *(N. gonorrhoeae)*
▪ dysuria		▪ non-gonococcal urethritis *(C. trachomatis or Ureaplasma urealyticum)*

Gonorrhea is the main cause of urethritis among clinic attenders in most developing countries. In recent years, however, as diagnostic techniques for chlamydia have become more sensitive, the role of chlamydial and mixed infections in causing urethritis in developing countries is also becoming better defined.[4,5] Some clinicians rely on the characteristics of urethral discharge to differentiate between gonococcal and non-gonococcal urethritis (NGU). Gonococcal urethritis tends to be more purulent and NGU more mucoid. However, these clinical signs are not sufficiently discriminatory to predict the etiology or cause of urethral discharge in a given patient.[6] In addition, they can be confounded by prior, ineffective treatments patients may have taken before coming to a clinic.

Two examples of flowcharts for urethral discharge are shown in Figures 1 and 2. The first example *(Figure 1)* is a simple syndrome management treating every man with a complaint of urethral discharge for gonococcal and NGU. A sequential treatment (first, treatment for gonorrhea and, if this fails, treatment for NGU) has been the policy in the past in some countries in order to limit unnecessary treatments. However, because of a large proportion of missed chlamydial infections, and because many patients fail to come back, this approach can no longer be recommended.

In the second flowchart *(Figure 2),* Gram stain is added to a syndromic approach. Depending on the result of the Gram stain, a syndromic treatment or a treatment for NGU will be given. This approach offers the advantage of reducing unnecessary treatments (including expensive gonorrhea drugs) for the patient and his partner by increasing the specificity of the flowchart.

A flowchart including Gram stain can only be considered when laboratory facilities are available. Results should be given within a reasonable time so that patients do not have to return to the health facility for treatment the next day.

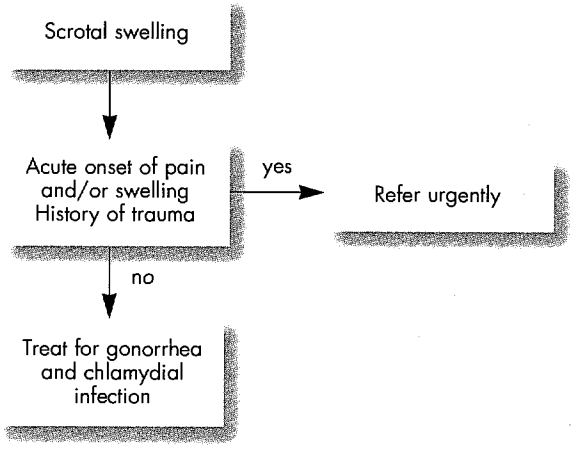
EPIDIDYMITIS: A COMPLICATION OF UNTREATED URETHRAL SYNDROME

- scrotal pain
- swelling of scrotum
- red + edematous scrotum
- urethral signs
- same as urethral discharge syndrome

Acute epididymitis in men ages 15 to 35 is most often STD-related.[7] In the 1930s, before antibiotics were available, epididymitis occurred in 10 to 30 percent of cases of gonococcal urethritis.[8] Figure 3 shows an example of a flowchart for epididymitis.

Figure 3
MANAGEMENT OF SCROTAL SWELLING

Nambia



Note: It is important to exclude non-infectious causes of a swollen scrotum, which include surgical emergencies such as testicular torsion or trauma.

LOWER GENITAL TRACT SYNDROME (LGTS) IN WOMEN

- vaginal discharge
- lower abdominal pain
- dyspareunia
- dysuria
- itching
- abnormal vaginal and/or cervical discharge
- vaginal inflammation
- cervical friability
- cervical motion tenderness

cervicitis

- gonorrhea *(N. gonorrhoeae)*
- chlamydial infection *(C. trachomatis)*

vaginitis

- trichomoniasis *(Trichomonas vaginalis)*
- bacterial vaginosis *(Gardnerella vaginalis,* anaerobes, *e.a.)*
- candidiasis *(Candida albicans)*

(Candida infections are generally not sexually transmitted.)

The symptoms of cervicitis and vaginitis overlap. Abnormal (in amount, color or odor) vaginal discharge is the symptom most commonly presented, but it is more predictive for vaginitis than for cervicitis.[9,10] The sensitivity of the symptom vaginal discharge for cervicitis varies from 25 percent (prostitutes in Zaire)[11] to 48 percent (STD patients in USA).[12] Cervical mucopus and induced endocervical bleeding have a high specificity (83 to 99 percent) but a low sensitivity (1 to 43 percent) as clinical signs for cervicitis.[11,13] Examples of flowcharts for LGTS are shown in Figures 4 and 5.

Figure 4 shows a flowchart for situations in which a speculum examination is not possible. The most probable cause of a woman complaining of vaginal discharge is vaginitis. Cervicitis is a less frequent cause of a consultation for vaginal discharge, but the complications of untreated cervicitis are much more serious.

Several studies in pregnant and asymptomatic women have demonstrated that risk markers, rather than signs and symptoms, are predictive for gonococcal

and/or chlamydial cervicitis.[11,13] The World Health Organization proposed incorporating a risk assessment as part of the diagnostic flowcharts for symptomatic women to increase their sensitivity. With this flowchart, a woman with a complaint of vaginal discharge is treated systematically for vaginitis (the most probable cause of vaginal discharge and the reason for her visit to the health center), but at the same time her risk for cervicitis is assessed. If her risk assessment is positive, she will receive treatment for gonococcal and chlamydial infection as well. The risk assessment flowchart for LGTS still needs more validation and adaptation to different cultural settings. The feasibility and acceptability of asking these highly personal questions (such as number of partners) should also be assessed.

In situations where a speculum examination is possible, the clinician can try to differentiate between various etiologies of vaginal discharge. The clinical sign mucopus, however, is not sensitive enough to be the only indication for cervicitis treatment *(see Figure 5)*.

An alternative for differentiating etiologies for vaginitis can be offered by simple laboratory tests, if the infrastructure is available. Direct examination of a vaginal wet mount is useful for detecting trichomonads and yeast forms. Determination of the vaginal pH and amine odor with 10 percent potassium hydroxide solution can be helpful in the diagnosis of bacterial vaginosis. But no simple laboratory test has been developed so far for detecting cervicitis. Adding Gram stain for the detection of intracellular gram-negative diplococci or leukocytes in the endocervix does not offer any advantage, as the sensitivity will drop dramatically.[9,10] The leukocyte esterase dipstick, which has a good sensitivity for detecting male urethritis,[14] had a sensitivity of only 47 percent for the detection of cervicitis.[15]

Figure 4

EXAMPLE OF A FLOWCHART FOR THE MANAGEMENT OF VAGINAL DISCHARGE

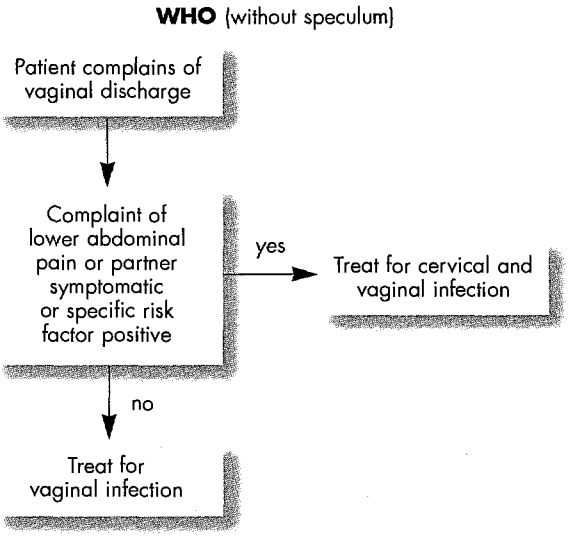
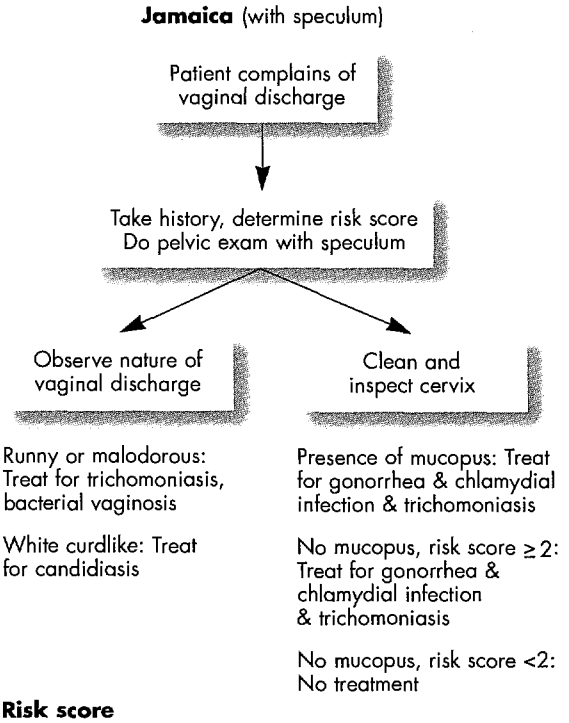


Figure 5

EXAMPLE OF A FLOWCHART FOR THE MANAGEMENT OF VAGINAL DISCHARGE



Risk score

Partner has urethral discharge	2
<21 years	1
New partner in last 3 months	1
>1 partner in last 3 months	1
Not living with steady partner	1
Total	

PELVIC INFLAMMATORY DISEASE (PID): A COMPLICATION OF UNTREATED ENDOCERVICITIS

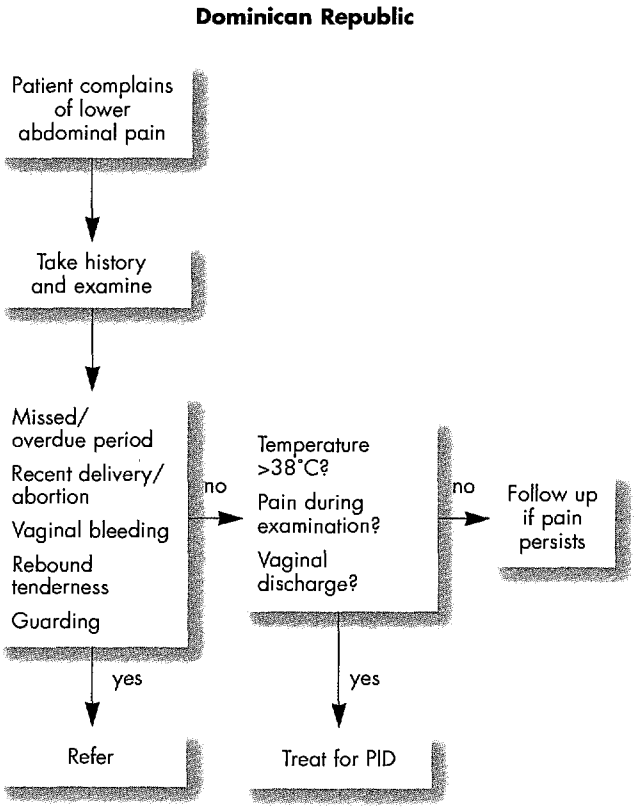
Common Symptoms	Common Clinical Signs	Most Common Causes (etiology)
▪ lower abdominal pain ▪ dyspareunia ▪ irregular bleeding	▪ adnexal + cervical motion tenderness ▪ vaginal or cervical discharge (sometimes) ▪ fever	▪ same as cervicitis + gram-negative and gram-positive anaerobes

PID is a common complication of untreated gonococcal and/or chlamydial cervicitis and results in tubal scarring and occlusion. This can lead to ectopic pregnancy—a serious, possibly life-threatening complication. Most infertility problems in the developing world are attributed to prior upper genital tract infections.[16]

An example of a clinical flowchart for detecting PID is shown in Figure 6. Because of the serious complications of PID, the flowchart should start with a very sensitive symptom. Lower abdominal pain is more sensitive for PID than fever.[17] It is important that surgical and obstetrical emergencies such as peritonitis and extra-uterine pregnancy are immediately referred.

Many studies have tried to describe a "typical" clinical picture for the different etiological diagnoses of GUS, but have failed.18-22 Descriptions such as regular shape, smooth base, undermined edge, friability, tenderness and purulence are not sufficiently discriminatory (even for experienced clinicians) to make an etiological diagnosis in most cases. In a study in South Africa of 210 patients with genital ulcers, clinical diagnosis was compared with a gold standard laboratory test. Clinical diagnosis had a positive predictive value

Figure 6
EXAMPLE OF A FLOWCHART FOR THE MANAGEMENT OF ABDOMINAL PAIN



Genital Ulcer Syndrome (GUS)

Common Symptoms	Common Clinical Signs	Most Common Causes (etiology)
genital ulceration with or without pain	genital ulcer on penis or scrotum in men and on labia, vagina or cervix in women	syphilis *(Treponema pallidum)*
	bubo (inguinal adenopathy)	genital herpes (herpes simplex virus)
		chancroid *(Hemophilus ducreyi)*
		lymphogranuloma venereum *(Chlamydia trachomatis L1-L3)*
		donovanosis *(Calynomato-bacterium granulomatis)*

of 89 percent for chancroid, 47 percent for syphilis and 19 percent for genital herpes.18 Dual infections were common, making an etiological diagnosis even more difficult. Without sophisticated laboratory tests, an etiological diagnosis of GUS is impossible.

The relative frequencies of the different causes of GUS vary between geographical areas *(see Table 1 on page 164)* but can also vary in time. For example, two studies on the etiologies of GUS, in Rwanda in 1986 and 1992, found that there was a shift in the relative frequencies of the different etiologies. As the prevalence of HIV infection increased, herpes became more important as an etiology of GUS.[23]

In many developing countries, the etiologies of GUS most frequently found are syphilis and chancroid. Both are treated with simple antibiotics (erythromycin and benzathine penicillin, respectively).

An antiviral therapy for herpes is not available in most primary health care settings. It is important to treat for chancroid and syphilis, even if some of the genital ulcers treated are actually caused by herpes.

In Rwanda, three different approaches were compared for the management of syphilis and/or chancroid. The syndromic approach *(Figure 7)* resulted in 99 percent of the patients with syphilis and/or chancroid correctly managed. For the approach based on the result of a Rapid Plasma Reagin (RPR) test (if RPR positive, treat

Figure 7
Example of a flowchart for the management of genital ulcers

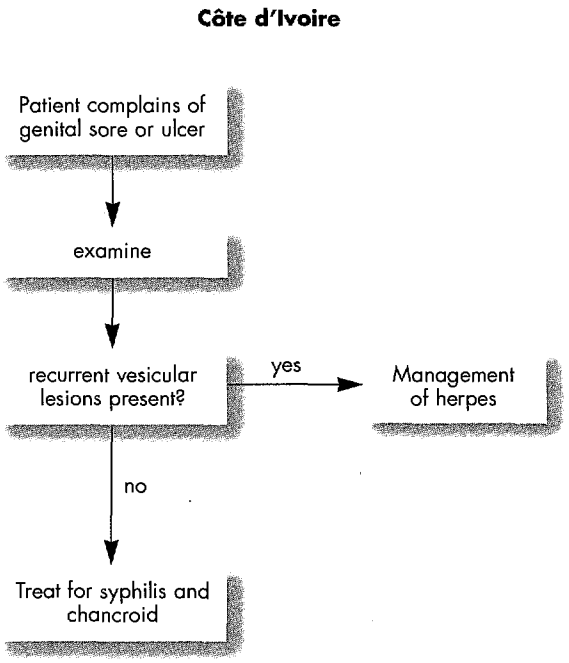


Table 1

PROPORTION OF DIFFERENT ETIOLOGIES OF GUS AS SINGLE OR MIXED INFECTION IN DIFFERENT COUNTRIES.

Swaziland	44	14	12	11	15
1983[19] n=155	(2)	(1)	(1)	(1)	
Rwanda, men	18	16	7	15	36
1989[20] n=110	(5)	(5)	(3)	(1)	
Malaysia	9	7	2	19	61
1991[21] n=249	(0.8)	(1.2)			
Thailand	36	1	0	0	52
1983[22] n=120					

for syphilis, if RPR negative, treat for chancroid) and for a clinical etiological approach, the proportions of correctly managed patients were 82 percent and 38 percent, respectively.[23]

Including an RPR test in a hierarchic model is not an improvement in genital ulcer case management, because many chancroid cases are missed. However, based on the Rwanda data, including an RPR test in a syndromic approach (treating all RPR positive patients for **both** syphilis and chancroid, and all RPR negative patients for chancroid alone), leads to a reduction in unnecessary syphilis treatment of patients and their partners.[23]

CONGENITAL STD SYNDROMES

See Chapter 9 for information on these syndromes.

COMPREHENSIVE CASE MANAGEMENT

In addition to diagnosis and treatment, comprehensive case management includes partner treatment, health education, and condom education, promotion and distribution. To remind health care workers of these aspects of case management, short messages could be added to the flowchart as shown in Box 2.

PARTNER TREATMENT

Partners of patients with an STD are likely to be infected themselves and should be offered treatment. Partner notification and referral can be one of the most important ways to detect and treat asymptomatic patients. Confidentiality, a nonjudgmental attitude and the absence of coercion are important for the success of partner notification. WHO recommends that epidemiological treatment (treatment based solely on the diagnosis of the index patient without any laboratory investigation) be given to all partners.[2]

An important implication of the low positive predictive value of some flowcharts is the over treatment

Box 2

Risk Assessment for Cervicitis

If+

- Treat for cervicitis
- Educate on compliance and risk reduction
- Promote and provide condoms
- Give partner referral cards and explain

of partners, resulting in unnecessary drugs given and the psychological cost of inappropriate labeling *(see Chapter 11)*.

Health Education

Patients seeking STD treatment may be particularly receptive to educational messages, recognizing the personal vulnerability evidenced by their symptoms. With HIV in the picture, people are more likely to welcome advice. Health education focuses on reducing risky behavior such as through the use of condoms or other mechanical barriers, and stresses the importance of partner treatment *(see Chapter 10)*. As time is usually very limited during a consultation, there is a real danger that this opportunity for face-to-face education will be missed.

Condom Distribution

The global effectiveness of condoms for preventing STDs depends on the efficacy of the method and user acceptability. Condom demonstration by the health care provider during the contact with the STD patient is a good way to recruit new users *(see Chapter 5)*.

CONCLUSION

The syndromic approach makes it possible for almost every health care worker to offer prompt diagnosis and treatment to patients with STD symptoms. Because it is simple, rapid and does not require sophisticated laboratory tests, syndromic diagnosis and treatment is perfectly adapted to primary health care settings.

Through clinical flowcharts, syndromic guidelines can be distributed and implemented in a standardized way on a large—even national—scale. Moreover, flowcharts facilitate and improve training of health care workers in STD management.

A single, universally applicable model for STD flowcharts does not exist. Local data on etiology and antimicrobial susceptibility are needed to design an effective flowchart. The validity and cost-effectiveness of different approaches can in many situations be estimated from the literature or assessed in special studies. Before the introduction of new flowcharts, feasibility and acceptability should be assessed in the given health infrastructure. A flowchart will always be a compromise between diagnostic accuracy and technical and financial realities.

Genital ulcers in men and women and urethritis in men can be adequately managed using a syndromic approach based on symptoms and clinical signs only. For lower genital tract syndrome in women, the new concept of adding a risk score to the syndrome management holds promise as a more sensitive way to detect cervicitis. Ongoing validation and acceptability studies will further demonstrate the advantages of this approach compared with the classical clinical approach.

In many developing countries a syndromic approach for the management of patients with STD is currently being used, resulting in well accepted, quality STD care in primary health care settings. The achievements of an STD control program depend to a large extent on the successful management of STDs at a patient's point of first encounter with the health care system.

ACKNOWLEDGMENTS

Our special thanks go to Anne Buvé and Marie Laga of the Institute of Tropical Medicine, Antwerp, Belgium, for comments.

APPENDIX 1

WHO TREATEMNT RECOMMENDATIONS

Urethral discharge

Treatment for **gonorrhea** and **chlamydial infection**

Gonorrhea:

Ciprofloxacin 500 mg tab. as a single oral dose
or
Ceftriaxone 250 mg IM as a single dose
or
Cefixime 400 mg tab. as a single oral dose
or
Spectinomycin 2 g IM as a single dose

Alternative regimens which may be useful in some countries, depending on the prevalence of resistant gonococci:

Kanamycin 2 g IM as a single does
or
Trimethoprim (80mg)/sulphamethoxazole (400 mg) 10 tablets orally for 3 days.

Chlamydial infection

Doxycycline 100 mg tab. orally twice daily for 7 days
or
Tetracycline 500 mg tab. orally 4 times daily for 7 days

Alternative regimen for patients in whom tetracyclines are contraindicated:

Erythromycin 500 mg tab. orally 4 times daily for 7 days

Epididymitis

Treatment for **gonorrhea** and **chlamydial infection** *(see "urethral discharge")*

Lower genital tract syndrome

VAGINITIS: treat for **candidiasis** and **trichomoniasis/ bacterial vaginosis**

Candidiasis

Nystatin 100,000 units intravaginally daily for 14 days
or
Miconazole or clotrimazole 200 mg intravaginally daily for 3 days
or
Clotrimazole 500 mg intravaginally as a single dose

Trichomoniasis/Bacterial vaginosis

Metronidazole 2 g orally in a single dose
or
Metronidazole 400-500 mg orally twice daily for 7 days

CERVICITIS: treat for **gonorrhea** and **chlamydial infection** *(see "urethral discharge")*

Ciprofloxacin is contra-indicated during pregnancy

Doxycycline and tretracycline are contra-indicated during pregnancy

PID

Outpatient therapy: Treatment for **gonorrhea** and **chlamydial infection** *for 14 days* and Metronidazole 400-500 mg orally twice daily for 14 days.

Genital ulcers

Treatment for **syphilis** and **chancroid**

Syphilis:

Benzathine penicillin G 2.4 MU IM in a single session
or
Aqueous procaine penicillin G 1.2 MU IM daily for 10 consecutive days

Chancroid:

Erythromycin 500 mg tab. orally 3 times daily for 7 days

Alternative regimens:

Ciprofloxacin 500 mg tab. as a single oral dose
or
Ceftriaxone 250 mg IM as a single dose
or
Spectinomycin 2 g IM as a single dose
or
Trimethoprim (80 mg)/sulphamethoxazole (400 mg) 2 tablets twice daily for 7 days.

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CHAPTER 9

STDs and Pregnancy

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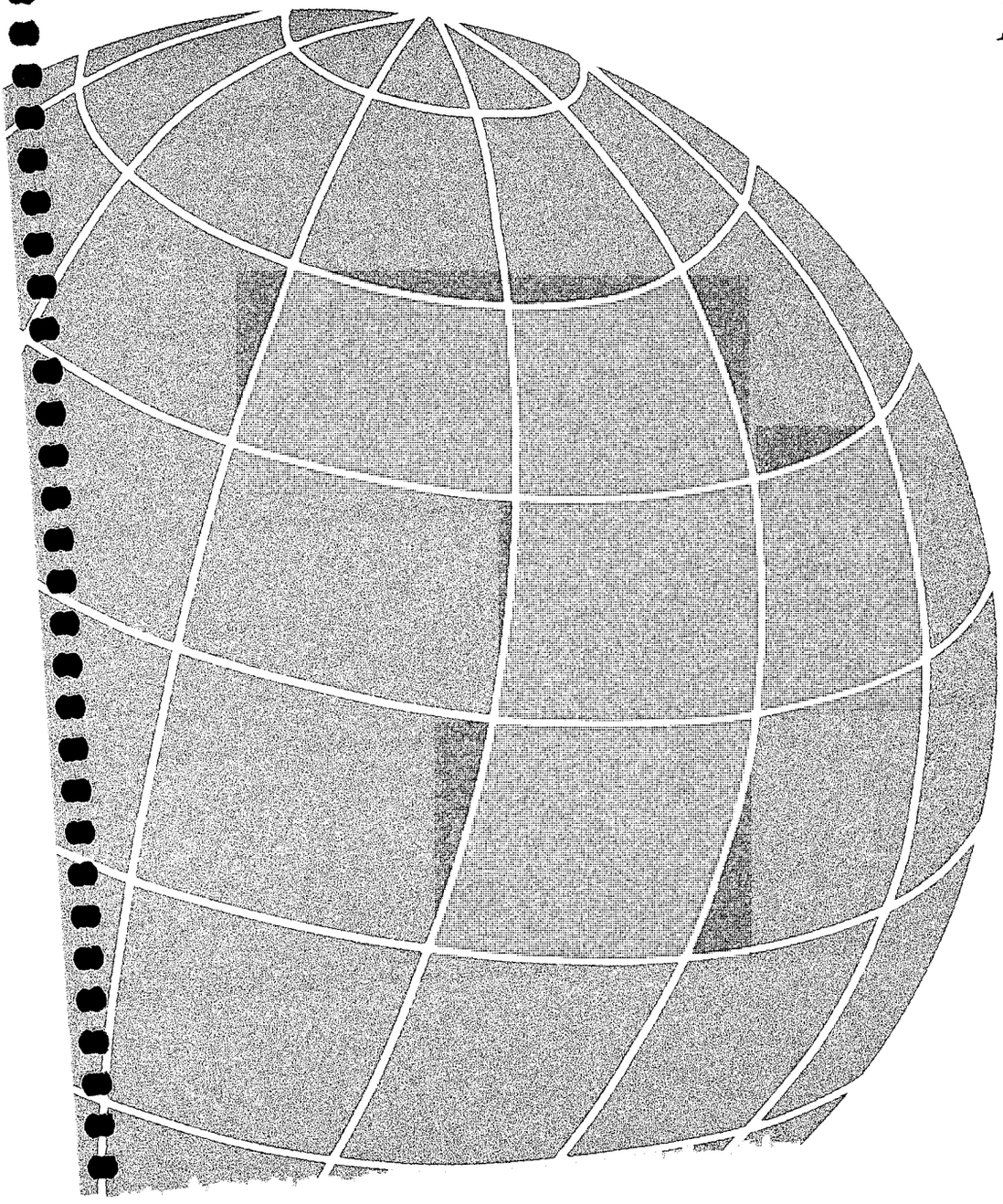

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STDs and Pregnancy

INTRODUCTION

This chapter focuses on the epidemiology, diagnosis and management of syphilis and gonorrhea in pregnant women and neonates, and strategies to reach women with STD services.

STD IN PREGNANCY: SYPHILIS

Prevalence Data

Syphilis prevalence rates between 3 percent and 19 percent have been reported in pregnant women from developing countries.

Impact of Syphilis on Maternal and Child Health

Untreated maternal syphilis may lead to spontaneous abortion, stillbirth, prematurity or congenital syphilis.

Diagnosis of Syphilis

For the purpose of routine screening of pregnant women, the use of only a qualitative rapid plasma reagin test (RPR) without confirmation with TPHA is sufficient and acceptable.

Treatment of Syphilis in Pregnant Women

Recommendations: Benzathine benzylpenicillin: 2.4 MU in a single dose by IM injection or aqueous procaine benzylpenicillin: 1.2 MU daily by IM injection for 10 days; in case of penicillin allergy, use erythromycin: 500 mg orally, four times daily for 15 days.

Control Programs for Congenital Syphilis

Routine serological screening and early treatment of both partners can prevent adverse pregnancy outcome due to syphilis. But syphilis control programs often are inefficient and ineffective.

Cost-Effectiveness of Syphilis Screening in Pregnancy

Screening and treating pregnant women for syphilis is highly cost-effective. In Lusaka, Zambia, the cost of preventing an adverse pregnancy outcome due to maternal syphilis was estimated at around U.S. $12 at a seroprevalence level of 10 percent.

STD IN PREGNANCY: GONORRHEA

Prevalence Data

In most African nations, prevalence rates of gonorrhea in antental clinic attenders range from 1 to 15 percent. Among industrialized nations, the U.S. has the highest rates, from 0.6 to 2.7 percent.

Impact of Gonorrhea on Pregnancy Outcome

Reports suggest a link between gonorrhea and premature delivery or very low-weight babies. However, trials with larger sample sizes are needed to provide conclusive evidence.

Gonococcal Ophthalmia Neonatorum (GCON)

Neonates acquire GCON at delivery during passage through the birth canal. If untreated, GCON can lead to blindness, but it is preventable by a simple prophylaxis program.

Prevention and Control

The following strategies can prevent and control GCON in neonates:

- Ocular prophylaxis at birth
- Diagnosis and treatment of GCON
- Diagnosis and treatment of maternal gonorrhea
- Primary prevention of gonoccocal infection among women

Cost-Effectiveness and Feasibility of Proposed Interventions

Although detecting and treating gonococcal infections in pregnancy reduces the incidence of gonococcal ophthalmia neonatorum and other maternal complications, it is expensive and not feasible in most areas of the developing world.

Ocular prophylaxis is more cost-effective *(see Table 4)*. It involves installing 1 percent silver nitrate drops or 1 percent of tetracycline ointment in the newborn's eyes within one hour after birth.

INTRODUCTION

In addition to being risk factors for the sexual transmission of HIV infection, STDs are also a major cause of morbidity, especially in women and children. Particularly urgent is the need to control fetal wastage and congenital abnormalities due to infections that are preventable and curable, such as maternal syphilis and gonorrhea.

The impact of other STDs, including *Chlamydia trachomatis, Trichomonas vaginalis* or bacterial vaginosis, on pregnancy outcome is still controversial (except for chlamydial ophthalmia neonatorum), and control measures are less obvious. Therefore, this chapter focuses on the epidemiology, diagnosis and management of syphilis and gonorrhea in pregnant women and neonates, and strategies to reach women with STD services.

STD IN PREGNANCY: SYPHILIS

Syphilis is a systemic, chronic infectious disease transmitted through sexual intercourse, from mother to infant during pregnancy and through transfusion of infected blood. The causative organism is *Treponema pallidum,* one of a small group of treponemes that are virulent for humans.

Prevalence Data

Syphilis prevalence rates between 3 percent and 19 percent have been reported in pregnant women from developing countries, with the highest rates found in southeastern sub-Saharan Africa.[1-8] Rates of congenital syphilis as high as 3,200 per 100,000 live births have been described in Addis Ababa, Ethiopia,[9] and 850 per 100,000 in Lusaka, Zambia.[10] In Zambia, 8.6 percent of infants under three months of age admitted to hospitals and 7.5 percent of neonates admitted to intensive care units had congenital syphilis. In Porto Alegre, Brazil, 2.3 percent of the newborns had clinical and/or laboratory incidence of congenital syphilis.[11]

Impact of Syphilis on Maternal and Child Health

The devastating effects of maternal syphilis infection on the fetus are well-known. Untreated maternal syphilis may lead to spontaneous abortion, stillbirth, prematurity or congenital syphilis. Vertical transmission of syphilis is common and is a major cause of fetal loss, perinatal and infant death, and long-term severe illness.[12,13]

The greatest effect of syphilis on pregnancy outcome is probably **spontaneous abortion.** Exact data on spontaneous abortions are difficult to obtain from developing countries, where a large proportion of women do not attend antenatal clinics before the pregnancy is "visible." Pregnant women with clinical signs or symptoms indicating a miscarriage often seek help outside maternal child health (MCH) facilities. Older data from Ethiopia suggest that five percent of all pregnancies are lost due to syphilis, whereas in Zambia, 19 percent of miscarriages may be attributable to syphilis.[14] A case-control study from Nairobi, Kenya, demonstrated an increased risk of 4.3 percent for spontaneous abortion in syphilis-seroreactive women.[15]

The relation between syphilis and **stillbirth** is well-documented. In Zambia, 42 percent of stillbirths have been attributed to syphilis, and congenital syphilis has been implicated in 30 percent of all perinatal deaths.[14] Data from Nairobi show an odds ratio of 4 for stillbirth in syphilis-seroreactive mothers. Table 1 shows data from a recent population-based study in Malawi that quantified the impact of syphilis on stillbirth, neonatal death and infant death. It is important to note that women with RPR titers of ≥ 1:8 were at greater risk for poor pregnancy outcome, indicating that more recent acquisition of syphilis infection may be more harmful for the fetus.

Table 1

Proportion of poor pregnancy outcome attributable to active syphilis* in HIV-negative women in Malawi[16]

Outcome	RR°	PAR+%
Fetal loss	8.8	22 (15-29)++
stillbirth		
- macerated	18.1	38 (18-59)
- fresh	7.3	19 (4-33)
neonatal death	4.5	11 (6-17)
- early	4.9	12 (5-19)
- late	3.4	8 (0-16)
- perinatal death	8.4	21 (15-27)
- postnatal death	2.4	5 (2-8)
infant death	3.3	8 (5-10)

* *active syphilis is defined as RPR-positive and titer > 1/8 prevalence in this population was 3.6 %*

\+ *PAR % = population attributable risk percent*

++ *95 % confidence intervals*

° *RR (relative risk) compared to women with negative syphilis serology*

Congenital syphilis occurs in approximately one-third of the newborns of pregnant women with untreated syphilis, although the stage of syphilis infection is probably the major determining factor. Congenital syphilis is a serious condition, disfiguring and debilitating, if not fatal. Since an infected child can be asymptomatic initially, diagnosis at birth is difficult, and the problem is underestimated in most hospitals.[16, 17]

Overall, it is estimated that one-third of syphilis-seroreactive pregnancies will result in fetal wastage, one-third in the birth of an infant with congenital syphilis and one-third in the delivery of a healthy, uninfected child. These proportions depend heavily on the stage of disease of the maternal syphilis, with primary and early syphilis being most infectious to the infant. It is less clear how many RPR reactive mothers with latent or already treated syphilis will have adverse pregnancy outcome or an infant with congenital syphilis.

Diagnosis of Syphilis

The primary lesion of syphilis typically presents as a chancre, from 10 to 90 days following exposure. The lesion is usually single but might be multiple, painless and associated with regional adenopathy. Untreated, the primary ulcer heals spontaneously in a few weeks. As a rule, all genital ulcers will be treated for syphilis and chancroid in most geographic areas of the developing world *(see Chapter 8)*. Within a few weeks or months, a variable systemic illness develops, characterized by low-grade fever, malaise, sore throat, headache, adenopathy and cutaneous or mucosal rash. People with serological evidence for syphilis but with no clinical manifestations have latent syphilis.[18]

Because the primary lesion is often painless and the secondary stage is characterized by aspecific signs and symptoms, a substantial proportion of infected people, particularly women, neglect to seek medical care and are only identified by serological screening. The most commonly used serological tests for screening are the rapid plasma reagin (RPR) test and the Venereal Disease Research Laboratory (VDRL) test, both non-specific tests *(for more details, see Chapter 12)*. Specific tests are the fluorescent treponemal antibody absorption test (FTA-ABS) and *T. pallidum* hemagglutination assay (TPHA), which are used as confirmatory tests.

For the purpose of routine screening of pregnant women, the use of only a qualitative RPR without confirmation with TPHA is acceptable and sufficient. A simpler version of RPR developed for finger-prick blood samples, "Teardrop," has been evaluated in field conditions. Because of its low sensitivity (69 percent) it cannot be considered a reliable alternative to the classic serum RPR test.[19]

Treatment of Syphilis in Pregnant Women

The duration of treatment for a seroreactive woman and her partner(s) depends on the stage of the infection. Since the majority of women identified through a screening program are in a latent stage, it is difficult to distinguish early from late syphilis. Furthermore, quantifying RPR titers, which may give an indication of disease stage, is not routinely done and often not feasible.

The following regimens are recommended:[20]

Box 1

- Benzathine benzylpenicillin: 2.4 MU in a single dose by IM injection;

  or

- Aqueous procaine benzylpenicillin: 1.2 MU daily by IM injection for ten days.

In case of penicillin allergy:

- Erythromycin: 500 mg orally, four times daily for fifteen days.

Treatment failures with penicillin therapy in preventing congenital syphilis have been reported, but the timing of therapy was not always mentioned.[12, 21] Treatment during the third trimester seems to increase the risk of treatment failure.[22] Some experts recommend two or three doses of benzathine penicillin at weekly intervals, especially after 20 weeks of pregnancy.

Diagnosis of Congenital Syphilis

Congenital syphilis has been divided into two clinical syndromes. The features that appear within the first two years of life comprise early congenital syphilis, whereas those that appear after two years comprise late congenital syphilis. Most syphilitic infants do not show signs at birth. Early clinical signs begin to appear in the third to the eighth week of life and consist of snuffles, palmar and plantar bullae, splenomegaly, pallor, joint swelling with or without pseudoparalysis, and cutaneous syphilis. However, none of these signs is entirely pathognomonic.[17]

In infants under the age of six months, a reactive RPR or VDRL test is very likely to indicate the presence of antibodies against syphilis, since false-positive reactions are rare in this age group. However, because maternal antibodies can be transferred to the infant, seroreactivity may not indicate active infection. Increasing the titers of reagin antibodies and/or IgM levels or more recent techniques such as PCR might help to identify active infection. These techniques are unavailable in most settings, and by testing the infant valuable time would be lost in the treatment of possible infection.

Treatment of Congenital Syphilis

Penicillin is the drug of choice for treating congenital syphilis. But, a standard dose of benzathine penicillin does not produce detectable penicillin levels in cerebrospinal fluid and is therefore considered inadequate for neonates with nervous system involvement. A dose of 50,000 U procaine penicillin IM per kilogram body weight daily for 10 days is the preferred/recommended treatment. A single IM injection of benzathine penicillin 50,000 U per kilogram body weight is an alternative in situations of noncompliance or possible loss to follow-up.[17] All neonates with a positive RPR or VDRL test should be treated unless the mother has received adequate treatment during pregnancy.

Control Programs for Congenital Syphilis

Adverse pregnancy outcome due to syphilis is preventable through routine serological screening and early treatment of both partners. Because of the high prevalence rate of syphilis in many developing countries, the harmful effects on the unborn child, and the availability of inexpensive and simple diagnostic and treatment facilities, most governments have adopted syphilis control programs for pregnant women. Nevertheless, comprehensive, effective programs are still lacking in most parts of the developing world.

In Zambia, data from two urban and two rural hospitals show that while 92 percent of pregnant women attended prenatal services, less than 30 percent were given a syphilis screening test. Of those found seroreactive, less than one-third were treated.[1] Similar findings were reported from Nairobi, where the existing centralized syphilis control program was found to be very inefficient.[32]

Box 2

The "Supposed to" Syndrome in Congenital Syphilis Prevention Programs

Example: Antenatal clinic with Fully Integrated Syphilis Control Service

National policy guidelines advocate screening all pregnant women during the first antenatal visit and treating all infected women. The clinics are in the community and thus are easily accessible. However, full realization of the program's goals is hampered by a lack of supervision and by the "supposed to" syndrome:

- **Women in need not identified**
  Pregnant women are *supposed to* attend antenatal clinics early in pregnancy but don't due to lack of confidence in the system and inadequate promotion by clinic staff.
- **Intervention not available**
  Clinic staff members are *supposed to* draw blood and transfer specimens to a laboratory but don't because of poor supervision, poorly organized systems to transport blood, lack of needles and other obstacles.
- **Test results not available**
  Laboratory technicians are *supposed to* conduct tests and communicate the results to clinic staff but don't because they think these tasks should not be part of their already heavy workload.
- **Utilization poor**
  Women are *supposed to* appear at the next antenatal visit and receive the results but don't because clinic record systems are poorly managed and organized.
- **Poor staff compliance**
  Clinic staff members are *supposed to* provide syphilis treatment and education on prevention and partner notification but don't because the drug supply is irregular, they consider talking about sexuality taboo and they have little time to spend with each client because of their heavy workload.

Barriers to congenital syphilis prevention programs include the following:

- Late attendance at antenatal clinics
- Logistical constraints, including shortages of laboratory equipment and supplies, drugs and transport facilities
- Lack of well-trained and motivated staff
- Virtually nonexistent partner notification systems
- The *"supposed to"* syndrome *(see Box 2)*

However, these barriers to an effective implementation of a congenital syphilis control program can be addressed and improved, taking into account the local conditions. Key strategies include encouragement of early antenatal attendance; serological testing followed by prompt treatment during the first visit; and active partner notification and treatment. Reports from Zambia[10] and Kenya[24] have demonstrated that it is possible to encourage health-seeking behavior using appropriate educational methods.

The other key element to success in the Zambian and Kenyan project was the decentralization of RPR testing. Sera were no longer sent to central laboratories but were tested promptly in the antenatal clinic by trained midwives. In addition, in Kenya educational materials were developed to convince mothers to bring

their partners in for treatment. These materials focused mainly on the responsibility of both parents to have a healthy baby *(see Chapter 11)*. After this system was introduced in Nairobi, the proportion of syphilis-reactive women and their partners who were adequately treated reached 92 percent and 50 percent, respectively.[24] The Zambian pilot study showed that under field conditions in a developing country, the prevention program helped reduce the adverse pregnancy outcome due to syphilis by two-thirds.

Cost-Effectiveness of Syphilis Screening in Pregnancy

In a high-prevalence urban area, STDs represent a substantial proportion of the entire disease burden of that population. Under the Healthy Life Days Lost per Capita ranking system, syphilis ranks fifth in importance after measles, HIV, malaria and gastroenteritis in a high-prevalence urban area.[34]

Screening and treating pregnant women for syphilis is known to be a highly cost-effective, inexpensive and feasible intervention for congenital syphilis, as illustrated by a demonstration project in Lusaka, Zambia. Hira and his co-workers calculated the cost of preventing an adverse pregnancy outcome due to maternal syphilis at around U.S. $12 at a seroprevalence level of 10 percent.[10] Even in countries with seroreactivity rates lower than 1 per 1,000, syphilis screening in pregnant women was reported to be cost-effective.[26]

Conclusions and Recommendations

- Prenatal screening and treatment of pregnant women for syphilis is cost-effective, even in low-prevalence areas, and should be applied globally.
- Intensive health education to motivate women to attend antenatal clinics early in pregnancy is an important component of a syphilis control program.
- Women have to be tested and treated as early as possible in pregnancy. Performing a qualitative RPR/VDRL test on the spot while the woman is waiting for the result can enhance the program's effectiveness.
- If the screening test is positive, treatment with benzathine benzylpenicillin 2.4 MU IM must be given immediately. If the patient is more than 20 weeks pregnant, treatment should be repeated after one week.
- In areas with a high prevalence and incidence of syphilis, repeat screening is recommended in the third trimester.
- Partner notification and treatment is an important strategy *(see Chapter 11)*.
- Unless both partners are treated adequately, a baby born to a seroreactive mother should be treated with 50,000 U procaine penicillin IM per kilogram body weight daily for ten days. A single IM injection of benzathine penicillin 50,000 U per kilogram body weight is an alternative therapy in situations where noncompliance or loss to follow-up is a possibility.
- Internal quality control of the RPR/VDRL tests should be included in every program. If possible, samples should be sent regularly to referral laboratories for external quality control.

STD IN PREGNANCY: GONORRHEA

Prevalence Data

Prevalence rates of gonococcal infections in pregnant women show wide geographical variations. Among the industrialized countries the United States has the highest rates, ranging from 0.6 to 2.7 percent. In most European countries the gonorrhea prevalence rate in pregnant women is virtually always below one percent.

In most African countries prevalence rates in antenatal clinic attenders range from 1 to 15 percent.[2,27-30] The paucity of data published from other continents suggest that some, but not all, countries have prevalence rates similar to those of African populations.[31] Although most of these studies were done in urban settings, high rates also have been documented in rural areas in Cameroon, for example.[32] Gonorrhea rates vary not only between different countries, but also differ greatly within a developing country.

Overall, gonococcal infection remains a common STD in the developing world, and the gap with the western world (at least Western Europe, where gonorrhea is disappearing) is only increasing.

Impact of Gonorrhea on Pregnancy Outcome

Earlier reports (mostly retrospective studies and case reports) have suggested an association between maternal gonorrhea and premature delivery.[33, 34] A case control study conducted in Kenya on the association of specific sexually transmitted diseases with preterm birth confirmed these previous findings.[35] Women with gonorrhea had a threefold increased risk to deliver a premature baby. A more recent, larger study in the same setting showed that maternal gonococcal infection was associated with an increased risk (odds ratio 3.2) of very low-weight babies (< 1,500 g), but not with prematurity (all babies < 2,500 g included).[36]

The role of maternal chlamydial infection in prematurity is more debatable. Only women with chlamydial infection with elevated IgM level were found to have an increased risk for prematurity.[37] Therefore, proposing public health interventions specifically aimed at preventing premature delivery caused by *N. gonorrhoeae* and *C. trachomatis* is arguable. However, selective intervention trials may contribute to a better understanding of their role, if any, in causing premature delivery. Only trials with a very large sample size will provide meaningful information, since the number of premature deliveries attributable to infection with these microorganisms is expected to be low.

There is increasing evidence that both gonococcal and chlamydial infection heighten the risk of **postpartum infections.** In a study conducted in Nairobi, 20 percent of delivering mothers developed clinical postpartum infection within seven to 28 days after delivery, and approximately 50 percent of these infections could be attributed to *N. gonorrhoeae, C. trachomatis* or both.[38] The magnitude of the contribution of postpartum infections to secondary infertility is still unclear.

Gonococcal Ophthalmia Neonatorum (GCON)

From a public health perspective, GCON is without any doubt the most important complication of gonorrhea in pregnancy. It is a frequent and severe condition that can eventually lead to blindness. It is important to understand that GCON is preventable by a simple prophylaxis program.

Definition and transmission from mother to child

Ophthalmia neonatorum is defined as a purulent conjunctivitis, with at least one polymorphonuclear cell per high power field on a Gram stain of an eye smear, in infants younger than 30 days old. Ophthalmia neonatorum can be caused by a number of pathogens, but the two main ones are *N. gonorrhoeae* and *C. trachomatis.* Although these organisms produce different patterns of disease (GCON tends to be more severe, more purulent and it has an earlier

Table 2

PREVALENCE OF MATERNAL GONOCOCCAL INFECTIONS AND TRANSMISSION RATE FROM MOTHER TO CHILD IN THE ABSENCE OF OCULAR PROPHYLAXIS

Kenya: Nairobi [27]	1019	67 (7 %)	28	47 %	3.6
Cameroon: Yaoundé [31]	296	40 (14 %)	12	30 %	4

onset), the etiological cause cannot be presumed from clinical signs alone.

Neonates acquire gonococcal ophthalmia neonatorum at delivery during passage through the infected birth canal. Occasionally diseases have been transmitted to infants delivered by Caesarean section after prolonged rupture of the membranes.[39] The transmission rate from mother to child in the absence of ocular prophylaxis has been estimated in two prospective studies in Africa *(Table 2)*. In Nairobi, gonococcal ophthalmia developed in 28 of 67 babies whose mothers had *N. gonorrhoeae* infections, a transmission rate of 47 percent. In Cameroon, 30 percent of exposed babies became infected. These transmission rates result in alarmingly high incidence rates of gonococcal ophthalmia neonatorum of 3.6 and 4 per 100 live births, respectively. By comparison, incidence rates of GCON in the Western world average 0.06 percent.

Clinical picture

Gonococcal ophthalmia begins one to thirteen days after birth. It is most often bilateral and purulent with the conjunctivae and eyelids swollen and hyperemic. If untreated, corneal involvement can appear as diffuse epithelial edema, giving the cornea a hazy, grayish appearance. Coarse white opacities (infiltrations) appear near the border of the cornea and the sclera, and may enlarge and become ulcerated by the end of the second or third week. These ulcerations can lead to perforation of the cornea, resulting in loss of vision. When new blood vessels invade the cornea, corneal scarring may occur. Effective treatment dramatically changes the course and outcome of the disease, usually with noticeable improvement within 24 hours.

It is difficult to estimate the risk of blindness associated with gonococcal ophthalmia. In 1880, the incidence of gonococcal ophthalmia in Stuttgart, Germany, varied from one to 14 percent, and 20 to 78 percent of the children in institutions for the blind had a history of the disease. After ocular prophylaxis at birth was introduced, the incidence dropped dramatically, and the percentage of institutionalized children with blindness caused by gonococcal ophthalmia steadily declined. Today in many developing countries, the incidence of gonococcal ophthalmia is still high, although blindness in children is not reported to be highly prevalent. However, blind children have a higher mortality rate, so the true extent of the problem would not be apparent in prevalence surveys. In a clinic-based study of 64 neonates with gonococcal ophthalmia, 16 percent proved to have corneal involvement.[40]

PREVENTION AND CONTROL

Four different strategies are possible for preventing and controlling gonococcal ophthalmia in neonates:

- Ocular prophylaxis at birth
- Diagnosis and treatment of GCON
- Diagnosis and treatment of maternal gonorrhea
- Primary prevention of gonococcal infection among women

Table 3

ATTACK RATES OF GONOCOCCAL OPHTHALMIA AMONG EXPOSED NEWBORNS RECEIVING SILVER NITRATE, TETRACYCLINE OR NO PROPHYLAXIS[41]

Newborns exposed to *N.gonorrhoeae* and those with gonococcal ophthalmia (%)**	71	5 (7)	66	2 (3)	60	28 (46.6)
Efficacy compared to no prophylaxis		85 %		94 %		

* *Incidence relates only to infants exposed to gonococcal infections and seen at follow-up visits.*
** *The difference between the silver nitrate and tetracycline groups was 4 percent (95 percent CI 3.4-11.4).*

Ocular prophylaxis at birth

Transmission of *N. gonorrhoeae* from the maternal cervix to the newborn's eyes can be interrupted by giving prophylactic drops immediately after birth. Three different regimens have been recommended: (1) silver nitrate 1 percent eye drops, (2) tetracycline 1 percent eye ointment, or (3) erythromycin 0.5 percent eye ointment.

Only the first two regimens have been evaluated prospectively in areas with a high proportion of multiresistant gonococcal strains, including penicillinase-producing *N. gonorrhoeae* (PPNG).[41] The results of this trial in Kenya demonstrated the equal and high efficacy of silver nitrate drops and tetracycline ointment in preventing gonococcal ophthalmia *(see Table 3)*. The attack rates among exposed newborns receiving silver nitrate or tetracycline were 7 percent and 3 percent, respectively. These findings are consistent with risk estimates of transmission from mother to child when prophylaxis is given.[39]

There are a number of explanations for reported failures of ocular prophylaxis to prevent neonatal ophthalmia. They include failure to instill the agent directly into the conjunctival sac, flushing of the eye after administration of silver nitrate (to prevent chemical conjunctivitis) and postpartum infection either by autoinoculation or from other infected persons.

Silver nitrate is inexpensive but it can be associated with benign chemical conjunctivitis. If the product is badly preserved (e.g., open bottles) it can evaporate, and increased concentration of the product can be toxic to the eyes. It is therefore recommended that silver nitrate be stored in a closed, dark bottle and transferred to small containers for daily use. Commercially available, single-dose ampoules are much more expensive and less readily available.

Tetracycline is non-toxic and may remain longer in the eye because it is an ointment. Multidose preparations are cheap and widely available in developing countries. Erythromycin ointment is expensive and less available in many countries.

Muhe and Tafari[42] have shown that a delay in prophylaxis of more than four hours after birth is associated with a four- to five-fold increase in risk of gonococcal ophthalmia. Prophylaxis therefore should be given as soon after birth as is practical—preferably within one hour—for both hospital and home births. Traditional birth attendants' kits should include a dispensing system for eye prophylaxis.

Ocular prophylaxis is operationally the most feasible and cost-effective strategy for preventing gonococcal ophthalmia in neonates. In areas with a

high prevalence of gonococcal infections in pregnant women, prophylaxis at birth for all infants should be introduced immediately as an initial step in reducing neonatal morbidity related to sexually transmitted disease in pregnancy.

Diagnosis and treatment of GCON

Early diagnosis and appropriate treatment of GCON are critically important because the infection can lead rapidly to blindness. Even in the case of a well-established, comprehensive ocular prophylaxis program, cases of GCON can occur. If cases of GCON are reported frequently, efforts should be made to reinforce or introduce 100 percent coverage of ocular prophylaxis.

WHO recommends the approach for management of ophthalmia neonatorum shown in Figures 1 and 2.[20] The rationale behind the flowcharts is that every severe case of ophthalmia neonatorum should be considered and treated as GCON unless *N. gonorrhoeae* can be excluded by gram stain. WHO has proposed several treatment regimens for GCON for areas with a high prevalence of PPNG:[20]

ceftriaxone: 50 mg/kg IM as a single dose
or
kanamycin: 25 mg/kg IM as a single dose
or
spectinomycin: 25 mg/kg IM as a single dose
+
tetracycline: 1% ointment for ten days

Some countries with low prevalence of gonococcal infections, such as the Netherlands, have adopted the strategy of diagnosis and treatment of complications in newborns. The neonatal infection is taken as the indicator of an infection in the parents; screening during pregnancy is not performed. In very low-prevalence areas with good health service coverage, this strategy may be the most cost-effective, but it has never been evaluated. Unfortunately, in most developing countries where gonococcal infections are still prevalent, diagnostic facilities and appropriate treatment regimens are not easily available. Control programs should adopt ocular prophylaxis strategy as a first priority, while still making treatment of GCON available.

Case finding and treatment of gonococcal infections during pregnancy

Detecting and treating gonococcal infections in pregnancy has the advantage of reducing the number of cases GCON, as well as other maternal complications such as postpartum endometritis or premature delivery. Several limitations, however, make it difficult to define precise strategies for finding and treating gonorrhea in women.

First, more than half of pregnant women with gonococcal infection are asymptomatic, and clinical signs associated with this infection (such as vaginal discharge or cervical mucopus) are not sufficiently sensitive or specific.[43] Vuylsteke and co-workers demonstrated that the classic WHO flowchart that starts with vaginal discharge as a complaint has a very low sensitivity and specificity for detecting gonococcal cervicitis, when used as a screening tool in both low- and high-risk women.[43]

Furthermore, the gold standard diagnostic test for gonococcal infection in women is bacteriological culture, which is neither available nor practical in most antenatal care settings. At present, a test to diagnose gonococcal and/or chlamydial infection in women (pregnant or non-pregnant) that is simple, rapid, affordable and valid does not exist. Some encouraging data from Zaire and Tanzania showed that diagnostic approaches which involve epidemiologic risk markers resulted in an acceptable validity, but further field evaluation in different cultural settings is needed.[43, 44] *(For further discussion, see Chapter 8.)*

Figure 1

Neonatal Conjunctivitis (without microscope)

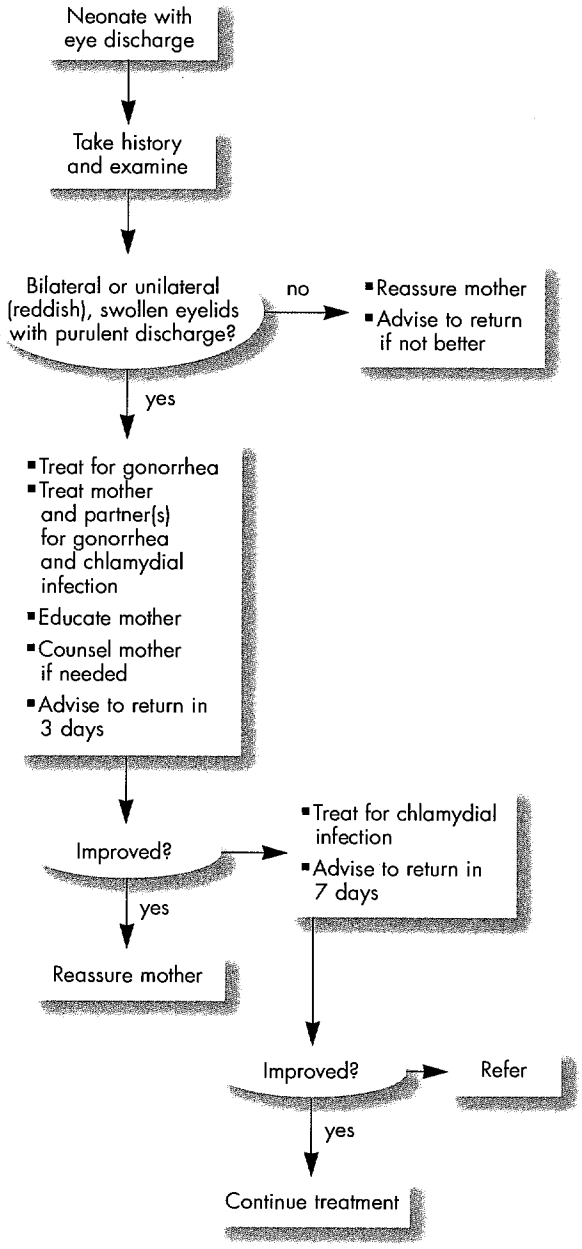
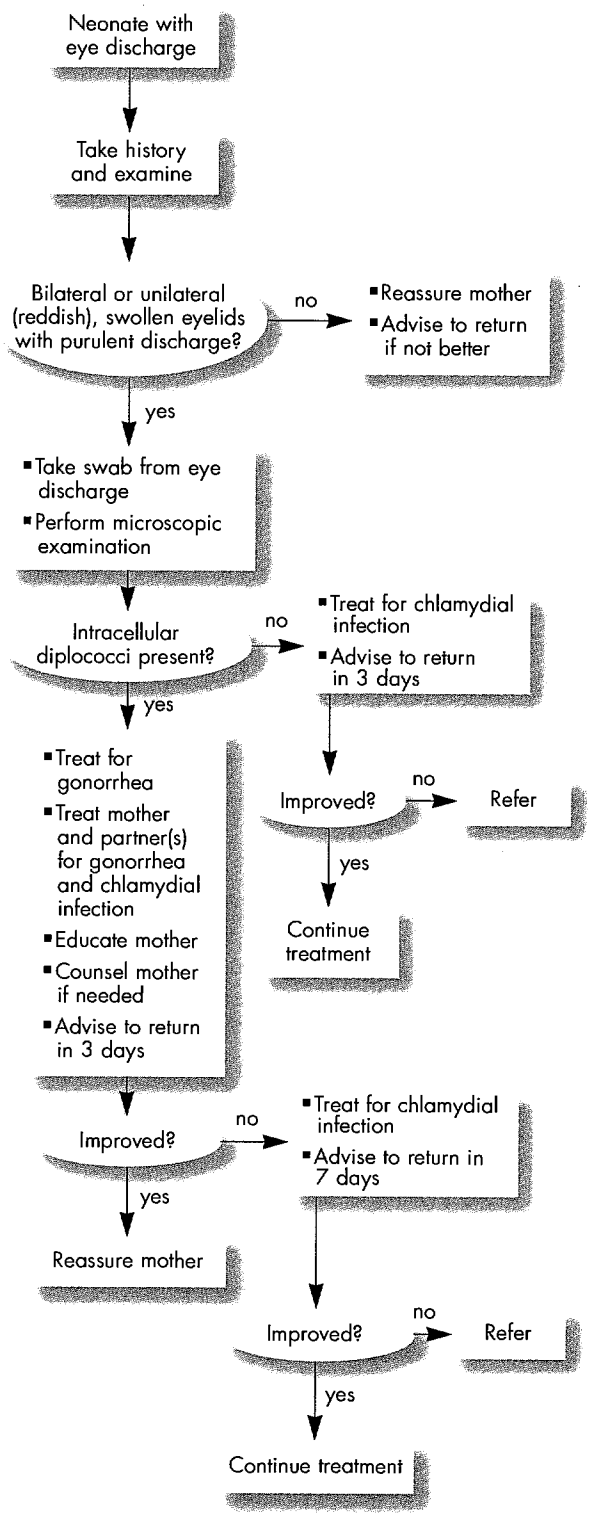


Figure 2

Neonatal Conjunctivitis (with microscope)



Mass treatment of gonococcal infection during pregnancy would only be indicated if it were shown to be more cost-effective than other detection programs. Considering the expensive and often unavailable antibiotics required for such a program (because of the limited options for treatment of gonorrhea during pregnancy), this strategy is not advisable. An additional argument against this strategy is women's lack of involvement in the diagnosis. The lack of a diagnosis also precludes the notification of partners.

Prevention of gonorrhea in women

In principle, women can be prevented from acquiring gonococcal infection through prevention (condom use and/or behavior modification). Prevention has not received high priority in STD control programs in the past, and, therefore, has not been very successful. With the emergence of a lethal and incurable viral STD—HIV—major efforts have been invested in promoting condom use and safer sexual behavior.

Data on the reduction of gonorrhea prevalence in pregnant women as a result of AIDS campaigns are not yet available. It should also be stressed that women are often at risk for gonococcal infection because of the sexual behavior of their stable male partner rather than from their own sexual behavior. In these cases, partner reduction messages are irrelevant for women.[3]

Cost-Effectiveness and Feasibility of Proposed Interventions

Although detecting and treating gonococcal infections in pregnancy reduces the incidence of gonococcal ophthalmia neonatorum and other maternal complications, it is a very expensive (if the goal is to reduce gonococcal ophthalmia) and operationally complicated strategy. Currently, it is not feasible in most areas of the developing world.

In Table 4, the cost of ocular prophylaxis is compared with the cost of early diagnosis and treatment of gonococcal ophthalmia in a group of 1,000 women with a prevalence of gonococcal infection of 10 percent. The cost for 1,000 prophylactic regimens is U.S. $100 for silver nitrate 1 percent drops (single-dose wax ampoules ophta doses) and U.S. $50 for tetracycline 1 percent ointment (multidose tubes for ten babies—U.S. $0.5 per tube). The price of one treatment regimen for gonococcal ophthalmia varies from U.S. $5 (125 mg IM of ceftriaxone in a single dose) to U.S. $2 (75 mg of kanamycin plus topical tetracycline).[51] It is assumed here that the best conditions would apply, meaning that each case of gonococcal ophthalmia would be brought back to a healthcare facility and receive appropriate treatment.

The total cost of the three programs: silver nitrate, tetracycline and no prophylaxis for a group of 1,000 women (with a prevalence of gonorrhea of 10 percent) would be U.S. $135, U.S. $65 and U.S. $235 respectively. This results in a cost per adverse outcome averted of U.S. $2.9, U.S. $1.4 and U.S. $5. Indirect costs of visual impairment due to late or inadequate treatment are not taken into account.

It is clear that the strategy of ocular prophylaxis is more cost-effective than early diagnosis and treatment. Furthermore, it is more convincing on humanitarian grounds, especially in areas where efficacious drugs are not readily available. In low-prevalence areas of maternal gonococcal infection (less than 1 percent), the cost of ocular prophylaxis may be higher than that of treating the cases of gonococcal ophthalmia that occur. But, without adequate treatment, the potential risk of blindness warrants further use of ocular prophylaxis in all countries where the health care coverage is not optimal.

Table 4

ESTIMATED COSTS OF CONTROL OF GONOCOCCAL OPHTHALMIA NEONATORUM (GCON) FOR 1,000 PREGNANT WOMEN WITH A PREVALENCE OF GONOCOCCAL INFECTION OF 10 % [45]

Incidence of GCON in newborns* (with and without prophylaxis)	7 %	3 %	47 %
Prophylaxis cost of 1 dose	U. S. $0.10	0.05	-
Prophylaxis cost for 1,000 newborns	U. S. $100	50	
Number of newborns developing GCON*	7	3	47
Treatment of GCON/case**	U. S. $5	5	5
Treatment of all cases of GCON**	U. S. $35	15	235
Total cost of prophylaxis and/or treatment	U. S. $135	65	235
Cost per adverse outcome averted***	U. S. $2.9	1.4	5

* *Incidence rates based on Nairobi clinical trial* [27, 41]
** *Optimal treatment for gonococcal ophthalmia neonatorum is chosen: ceftriaxone - 125 mg IM single dose* [41]
*** *Adverse outcome includes only gonococcal ophthalmia here*

CONCLUSIONS AND RECOMMENDATIONS

- Gonorrhea is still prevalent among pregnant women in many developing countries. It can result in premature birth and postpartum endometritis; without ocular prophylaxis, 30 to 50 percent of exposed babies will develop GCON, a potentially blinding condition.
- Ocular prophylaxis at birth is a highly effective, simple and relatively inexpensive strategy to prevent 95 percent of GCON. This includes installation of 1 percent silver nitrate drops or 1 percent of tetracycline ointment in the eyes of the newborn within one hour after birth for all births both in the hospital and at home. Because of the high prevalence rates of gonorrhea in women and the low availability of effective treatment for GCON, this strategy is recommended for all areas of the developing world.
- Cases of neonatal conjunctivitis should always be considered gonococcal unless proven otherwise, and effective therapy (local and systemic) should be administered without delay to prevent damage to the eye.
- In addition to reducing GCON, controlling gonorrhea among pregnant women may also reduce GCON and also other maternal complications such as prematurity or postpartum infection. Although case finding strategies based on risk assessment seem promising, precise recommendations for the developing world cannot be made at this stage.

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CHAPTER 10

Behavior Change in the Clinic Setting

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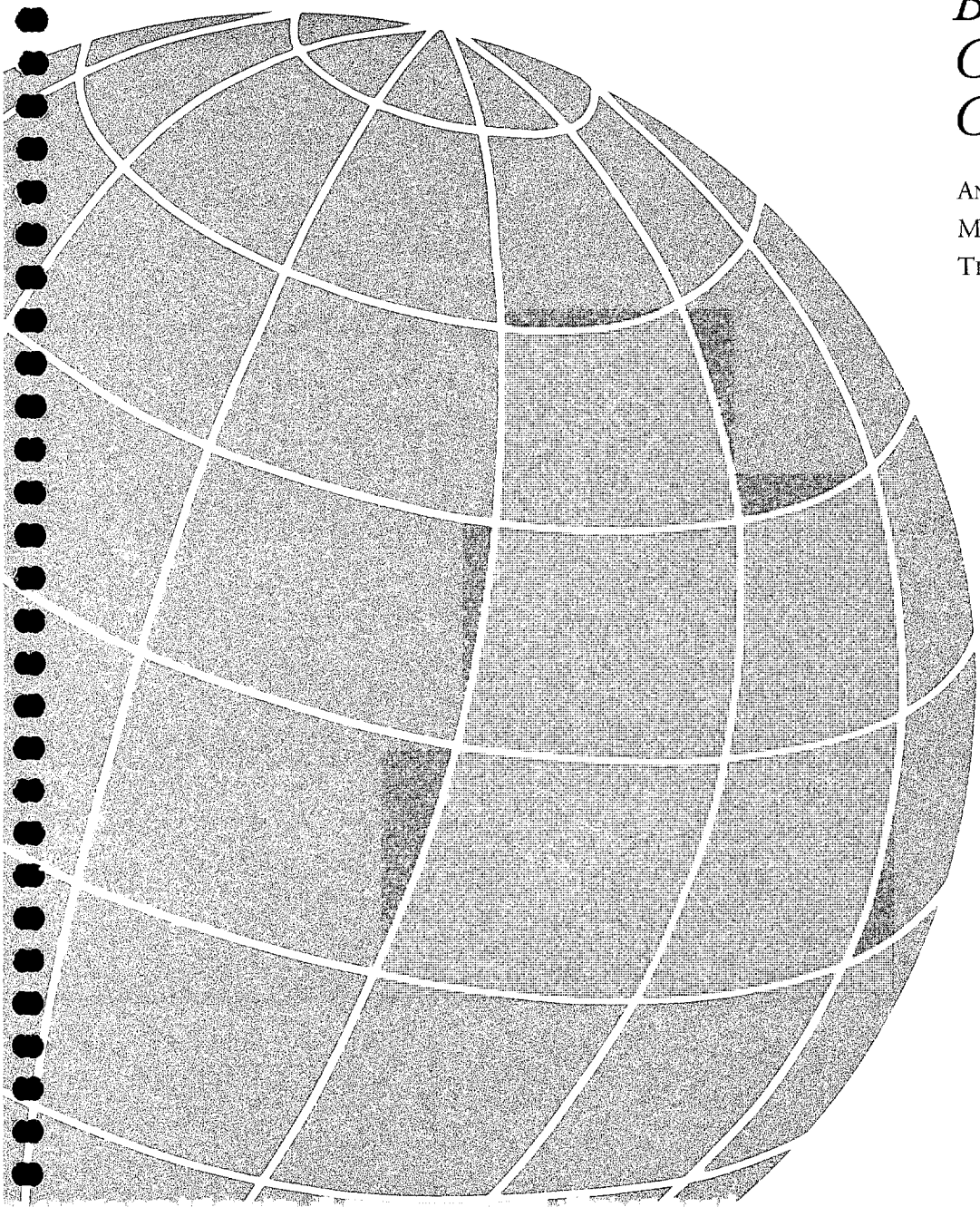

preview CHAPTER 10

Behavior Change in the Clinic Setting

INTRODUCTION

Patient education is the missing component of much STD care around the world. This chapter is intended to provide STD clinic managers and staff with information to help them design, implement and evaluate STD patient education at their clinic sites.

THE ROLE OF THE CLINIC MANAGER

For patient education to be effective, the clinic manager must play an active and supportive role. This includes allocating resources for educational materials, ensuring that providers have the time to educate patients and rewarding educational efforts.

THE RATIONALE FOR PROVIDING CLINIC-BASED EDUCATION ABOUT STDS

Among the reasons for educating within the clinic setting are the following:

- It is efficient.
- Often a patient is ready and receptive.
- There is a synergy of care and prevention.
- Community efforts are reinforced.

GOALS AND OBJECTIVES OF PATIENT EDUCATION IN STDS

The main objectives:

- Resolve the patient's current infection.
- Prevent a recurrence of the infection.
- Prevent its spread to others in the community.

EFFECTIVE PATIENT EDUCATION

General principles:

- Show respect and concern for the patient's safety.
- Make the education patient-centered.
- Address cognitive, affective and psychomotor learning domains.
- Use adult learning principles.
- Use multiple channels: visual, auditory and interpersonal.

The process of patient education

- Make an assessment.
- Establish priorities.
- Identify long- and short-term objectives.
- Identify barriers to learning.
- Assess the learning environment.
- Evaluate client progress.

Approaches to patient education

- Determine the appropriate providers: most staff members have an educational role to play.
- Determine the points of opportunity: education can occur throughout the patient's visit to the clinic.
- Determine content and educational techniques: patient needs and knowledge levels determine content. Provider-patient interpersonal communication weighs heavily.

Evaluating patient education at the clinic site

Although tests are helpful, a high knowledge score is no guarantee that a patient will not return with an STD. The most useful evaluational techniques are those that measure actual behavior change.

INTRODUCTION

Patient education is the missing component of much STD care around the world. In addition to understanding how to recognize STDs, patients must be motivated to prevent and properly treat them. Skillful approaches to patient education can nurture and sustain this motivation.

This chapter is intended to provide STD clinic managers and staff with information to help them design, implement and evaluate STD patient education at their clinic sites. The chapter sets patient education in a framework, providing indicators for effective patient education, case examples, caveats and an approach that maximizes the effect of patient education by using multiple channels and complementing community-based efforts.

The chapter offers practical approaches to a number of issues including the importance, aims and trademarks of effective patient education. In addition, the chapter discusses:

- How clinic-based patient education can contribute to behavior change in patients
- What providers need in order to do a good job of educating patients
- Important points to follow in designing behavior change messages

THE ROLE OF THE CLINIC MANAGER

Without the active support of the clinic manager it is difficult for clinic personnel to institute a successful program for patient education on STDs. The clinic manager is a facilitator of the process and the source of resources needed to provide quality patient education. Managers do this in the following ways:

- Allocate resources for patient education materials
- Allow providers time to educate patients
- Organize clinic facilities to allow for privacy and educational activities
- Reward efforts in patient education
- Include competence in patient education in the criteria for selected clinic positions
- Establish or support policies that protect patient confidentiality

Although clinic managers might not use all of the principles and approaches described here, the content of this chapter can help in guiding decisions about clinic programs, designing program evaluations and hiring people to design education programs. The manager familiar with these principles and approaches has the means to oversee the implementation of an effective patient education program.

THE RATIONALE FOR PROVIDING CLINIC-BASED EDUCATION ABOUT STDS

There are many reasons supporting the use of a clinic visit as an opportunity for patient education:

EFFICIENCY

Education within the clinic reaches patients where they are being treated and eliminates the need for additional patient or system transport, time and motivation.

PATIENT READINESS

A patient's decision to come to the clinic signals a level of concern that may provide the teachable moment. Evidence suggests that people are more willing to learn about a disease when they or someone close to them experiences its symptoms or consequences. Prior to coming to the clinic, many patients will have already sought the advice of friends or family.[1]

SYNERGY WITH COMMUNITY EDUCATION

Community educational efforts are reinforced when patients receive the same messages during their visit to the clinic.[2]

SYNERGY OF CARE AND PREVENTION

Patients are more accepting of prevention advice when they know they are getting good clinical care as well. This was confirmed in Zaire during a 1988-1991 commercial sex worker (CSW) intervention when women became more receptive to safe-sex messages after they recognized the high quality of the care they were receiving.[3]

The difference between treating STDs and managing them effectively is the difference between providing drugs alone or providing drugs **and** instruction about why they are necessary, how and when to take them, possible side effects, and what to do if there is no improvement. A clinic may claim that it provides high quality treatment of STDs. But closer scrutiny of patient response to treatment can reveal that the appropriate drugs are prescribed but patients often take them improperly because of poor education, and frequently resort to other treatment methods after the first attempt by the clinic provider fails.

In view of the relationship between HIV and STDs, the prevention and prompt and effective treatment of STDs have taken on increased importance. Clinic managers can contribute significantly to efforts to decrease the impact of HIV on communities by actively promoting, supporting and providing resources for effective patient education programs.

Box 1

WHY PROVIDE CLINIC-BASED PATIENT EDUCATION?

- It is efficient because it reaches the patient where the patient is.
- If you can prevent STDs, you can prevent HIV.
- The time is right. Patients are likely to be motivated to find out how to avoid the same discomfort in the future.
- Preventing future visits contributes to the community's overall productivity.
- Treatment is more likely to be effective if a patient understands the regimen.
- Effective patient education is part of delivering good STD care.

Education is the key to —

- Patients following treatment instructions
- Fewer complications due to STDs
- Fewer future infections

GOALS AND OBJECTIVES OF PATIENT EDUCATION IN STDS

The following are the main objectives of patient education in STDs:

- Resolve the current infection in the patient presenting to the clinic
- Prevent a recurrence of the infection in the patient
- Prevent the spread of that infection to others in the community

The overall goal of patient education is to halt the spread of STDs in the community. A decrease in STDs can mean a decrease in the number of stillbirths, premature births, ectopic pregnancies, infertility, cases of HIV infection and AIDS, and a range of other problems stemming from STD-related morbidity.[4]

Patient education in STDs can be divided into the categories of preventing future infections and managing the current infection. Preventing future infections requires sustained behavior change or the consistent practice of low-risk sexual behavior. Managing the current infection both prevents further transmission of the STD to others and prevents complications in the patient.[5] These efforts are most effective when accompanied by patient education that provides essential information and motivates the patient to follow treatment recommendations.[6]

Messages to prevent further infections should go hand in hand with correct management so that the patient is encouraged to adopt practices that will prevent a recurrence of STD. It is important to note that the patient may need emotional support. By providing this in a timely and effective manner, the provider can expedite the accomplishment of other patient education objectives.

There is much a patient needs to know including prevention measures, facts about STD transmission, symptoms and treatment *(see Box 2)*. It is well-known that even a mastery of the knowledge does not guarantee prevention of STDs. Motivation is important to the patient who needs it to consistently practice low-risk sexual behaviors.[7] And providers must develop the skills that are useful in motivating patients.

One aspect of patient education that is insufficiently recognized is the potential for a multiplying effect when patients take home materials and discuss what they have learned with family members and friends. If the community has an active outreach education program, this clinic-based education can reinforce those efforts.

Box 2

What the Patient Needs to Know

Prevention Measures	Condom use Partner choice Alternatives to penetrative sex
STDs	How STDs are passed between people Consequences of STDs Relationship of STDs and HIV/AIDS
STD Symptoms	What to look for and what it means
STD Treatment	How to take a medicine (with what other substance and for how long) Signs that call for a return to the clinic Importance of partner referral and treatment

EFFECTIVE PATIENT EDUCATION

Background

Counseling, advising and educating

There is a difference between counseling, advising and educating. "Counseling" is generally accepted by mental health professionals to mean in-depth, long-term and repeated interactions between a trained counseling professional and a patient covering topics that can be very broad in scope and emotional in nature. For this reason, the phrase "behavior change advising" is preferred. This conveys the idea that in the STD clinic setting there are usually more limited human resources available and the interaction between patient and health care worker may be brief as well as restricted to only one encounter.

Box 3

General Principles of Effective Patient Education

- The education shows respect and concern for the safety of the patient.
- The education is patient-centered.
- The education addresses three domains of learning: cognitive, affective and psychomotor.
- The education is delivered according to principles of adult learning.
- The education uses multiple channels (visual, auditory, interpersonal).

The discussion here centers on behavior change advising in the clinic setting as a viable and under-utilized approach to stimulating behavioral risk reduction. "Education" will be used here as a cover term that includes behavior change advising among other approaches (e.g., health talks, posters, brochures, audio cassettes, etc.). Since it is generally accepted that education as information-giving alone is not a sufficient prevention strategy, education in this context includes motivational messages and approaches to changing behavior as well as factual information.[8]

Telling a patient how STDs are transmitted and the treatment for the STD they have is considered informational. As the provider answers questions and addresses behaviors related to prevention and treatment, he or she moves along the continuum toward counseling. This session might include an advisory component, such as "it might be best to take your pills in the morning when you are more likely to remember them," or "it is important that you discuss condoms with your partner."

General Principles of Effective Patient Education

This next section addresses the main principles that should be followed in designing an effective patient education program. The box below summarizes the major points discussed:

The education shows respect and concern for the safety of the patient

Patients who present to clinics with STDs are often embarrassed if not remorseful about their condition.[9] There are all too familiar images of patients being admonished by the punitive physician or nurse who, with perhaps good intentions, wants to shame patients into behavior change. While this might be effective with a few, it is not likely to be successful with most patients. The basic premise on which patient education is based is that individuals deserve respect and need to feel comfortable in their learning environments if they are going to be able to listen, value what is heard and adopt new behaviors.[9]

Part of respect is not judging a patient. Providers who are sensitive to what it is like to reveal detailed sexual behavior information to a stranger are more likely to convey acceptance to the patient. This is often a challenge because of the provider's cultural norms or religious beliefs.

In addition to understanding and valuing the importance of treating patients with respect, providers also need to ensure privacy and confidentiality during the patient history taking and exam. A lack of privacy and confidentiality are among the most common complaints that patients voice about STD services.[10] Without privacy patients are less likely to provide an accurate history and might have difficulty absorbing information and instructions. Thus, the time spent getting a history and providing advice or information about private matters in a public setting is likely to be time wasted. Other consequences of failing to provide privacy, confidentiality and a respectful attitude are that the patients are less likely to return when they need to, have trust and confidence in the treatment offered, or refer peers and family to the clinic for services.

In a busy and under-staffed or under-funded clinic setting, it is a challenge to provide privacy. Taking whatever steps are realistic to improve the environment of confidentiality will go a long way. Although this will not likely reduce the social stigma attached to an STD infection, it will at least protect the patient from experiencing this stigma while they are seeking medical attention.

There are three major ways in which clinic managers can facilitate the provision of privacy and confidentiality for patients. First of all, they can ensure that all clinics are arranged physically so that there is some opportunity for a private conversation between patient and provider during the clinic visit. When space is limited, this requires creativity, but it is usually possible. Secondly, there must be policies and procedures in place that guarantee confidentiality of the patient's

Box 4

Case Example

Giving empathy to a young woman with vaginitis who is not married might be the antithesis of what an older nurse thinks she should do. She may think it is her duty to admonish the young woman and uphold prevailing moral judgments of her behavior. By allowing this to happen, the nurse is at risk of discouraging the young woman from sharing her fears and concerns, and asking important questions, thereby lessening her receptiveness to learning and behavior change recommendations.

clinic record. And last, staff must be guided by policies demanding confidentiality of information disclosed during the patient visit. These efforts to protect patients must be introduced and reinforced through training. Once the values of privacy and confidentiality have been institutionalized in the clinic, as shown through attitudes and supportive policies of providers, the benefits will be tangible in terms of patient satisfaction and the delivery of upgraded STD services.

The education is patient-centered

Patient-centered education takes into consideration the patient's values, culture, current knowledge, readiness to learn and style of learning. It gives priority to the needs of the patient rather than to the needs of the provider or institution. An important question for health providers to ask themselves when educating patients is, "Are we speaking the same language?" The different terminology used by patients and by health care workers as well as their differing perspectives on the importance or severity of an illness have an important effect on their ability to communicate with one another.

For example, some women may consider vaginal discharge to be normal even though it would be characterized by a practitioner as symptomatic of an STD. Some male patients may consider an STD to be cured once the symptoms have disappeared, even though this does not correspond with an STD practitioner's definition of cure. And the term used by a physician to describe an STD infection may not always correspond with the words a patient uses to describe an illness with the same symptoms.

It is sometimes difficult to understand the source of information that leads to the inaccurate ideas patients form about who is likely to transmit or become infected with an STD. It is important to know how these ideas, which may have emerged from both inaccurate and accurate medical information, are filtered by the patient and become popular concepts of illness and disease transmission.

For example, a stated medical recommendation to use a condom with high-risk sexual contacts may be understood as applying only to commercial sex and not to casual sex or sex barter. Perhaps the term "high-risk sex" is interpreted to mean anal intercourse and not vaginal sex no matter who the partner is. Under other circumstances sexual behavior may be linked to the locus of control, or the person making the decision when and how to have sex or whether or not to use a condom.[11] For example, a woman who has non-consensual sex with her male partner may not easily identify with recommendations to use condoms. In addition, it is important to remember that more often than not, the patient's perception of risk is not calculated in the terms scientists use to describe the probability of infection (e.g., risk, odds ratio) but rather is couched in individual or personal term tied to one's sense of vulnerability when exposed to a possible infectious agent.[12]

Cultural bias: The single most important first step is to acknowledge that everyone has cultural biases to a greater or lesser degree and that recognizing them is instrumental in reducing or eliminating their negative effect on patient communication. The health care worker is challenged to respect the point of view of each patient. By demonstrating this respect, the health care worker encourages and supports efforts of patients to communicate openly.

Cultural sensitivity: This refers to a heightened awareness of the patient's point of view as it stems from culture, and an active consideration of this perspective in the tone of all educational encounters with patients and in the configuration of services. What has to be considered are the beliefs about causes and cures for illnesses related to sexual intercourse or, alternatively, illnesses that have STD symptoms but are believed to be transmitted by non-sexual means and cured by traditional means outside of the clinic system. The fundamental strategy is to be aware of these belief systems. Once aware, the health care worker can look for ways to encourage appropriate health-seeking

Box 5

Common Myths About STDs

- One STD can be converted or turn into another.
- You can only get one STD at a time.
- All STDs including HIV are detected using one diagnostic test.
- Health care personnel can tell if a patient has HIV without testing.
- People with STDs always have symptoms.
- You can't have HIV and an STD at the same time.
- You can tell who has an STD/HIV by how they look or feel.
- You can tell who has an STD/HIV by their actions, occupation, social class or number of sex partners.

behavior including symptom recognition and prompt use of clinic services while not undermining or directly conflicting with traditional belief systems. This holds true unless these traditional practices are clearly shown to be harmful or counterproductive.[13]

STD beliefs: Erroneous beliefs surrounding illnesses transmitted by sexual intercourse can be extensive. Some of the frequently held myths that are important to understand and address during health education encounters include those in Box 5.

Customizing the approach: All too often providers satisfy their own need and tendency to communicate a list of facts and admonitions according to a formula or theory. It is critical that the provider begin by understanding the patient's current level of knowledge and how they usually learn. For example, do they read or do they like to talk and ask questions about what they want to know? By doing this, the provider avoids giving a lot of information that the patient either knows already, is not interested in, or does not understand. It is preferable that the provider initially spend time doing a brief assessment in preparation for any time spent on education. Conducting this assessment in a short time period requires skillful interview techniques that many providers need to learn through training. This subject is discussed further in the section in this chapter on "The Process of Patient Education."

Sensitivity to the psycho-social dimension of behavior and behavior change is one of the most challenging aspects of health education in the clinic setting. The process of building a psycho-social sensitivity on the part of members of the health care team is ongoing and involves both introspection and empathy for the realities confronting patients on a daily basis.[7]

Taking the concept of patient-centered education to the population level means that educational approaches directed to the entire clinic population reinforce the specific messages for target groups.[2] This information is usually presented in general terms and should always be complemented by specific action-oriented messages for distinct target groups. Most countries already have experience with general population education activities. These experiences show that education to encourage behavior change and reinforce these changes over time must also include tailored educational interventions for identified target groups. To develop programs of this nature, a collaborative effort with individuals with communications experience and/or expertise is advisable since communication methodology is beyond the scope of most STD clinic programs.

The education addresses three domains of learning: cognitive, affective and psychomotor

Attention to all three is required for education to be effective.

- The "mind" or cognitive domain includes ideas, facts and knowledge.
- The "emotions" or affective domain includes emotions and feelings.
- The "muscles" or psychomotor domain includes manual activities or skills-the "doing."[14]

Box 6

The Three Domains of Learning

Cognitive—patient needs to know the facts
Methods: Health talks and informational brochures

Affective (or attitude)—patient needs to deal with emotions or attitudes about an issue
Methods: Videotapes, audiotapes, group discussions or role plays

Psychomotor (or skills building)—patient needs an activity
Methods: Simulation training or skills practice such as condom use

Different educational methods are used to address different learning domains. For example, health talks and informational brochures are most suited to the cognitive domain of learning, also known as the knowledge aspect of the education process.

Videos, audiotapes, group discussions and role plays reach the affective or attitude domain. By hearing different opinions, and talking with or viewing others in similar situations, patients have the opportunity to grow in their attitudes and values, and deal with their emotions.

For the psychomotor aspects of the education process, a simulation training method such as teaching patients to put a condom on a model is most effective. To illustrate this approach to skills building, consider the example of the mechanics of cooking: if you want to learn to make a great dessert, simply reading about how to make desserts is generally much less useful than actual hands-on practice *(See Box 7).*

Box 7

Missing A Learning Opportunity

Mary just experienced symptoms of an STD. She went to the local clinic where she waited for two hours and saw the nurse for ten minutes.

During the exam and injection, the nurse told her that she should use a condom because Mary admitted that her husband sometimes goes with other women. After the nurse told her this, there was no time left for discussion.

"Great," thought Mary on the way home, "How will I ever tell him that?"

Mary was distraught. She didn't want to get another infection and she didn't want to talk to her husband.

What did the nurse think she was going to do? Work magic?

Advice To Mary's Nurse

Mary needed more than instruction.

She needed discussion, consolation and practice with feedback.

Of course she needed to know that a condom could prevent another infection (**"mind"**). But that was not enough.

She needed help with her feelings (**"emotions"**) about her husband's behavior and perhaps some suggestions about how to talk to him about it.

She also needed help with **HOW TO** do what she needed to do. She needed **practice,** actually practicing what she would say (**"muscle"**).

Box 8

Aspects of Comprehensive STD Patient Education

One. While waiting in the clinic waiting room or during her time alone with a provider (cognitive domain), the young woman with an STD would have the opportunity to hear about how one gets the disease, how to prevent it and why it is important to get a partner treated.

Two. She would then see a video, listen to an audiotape, or participate in a role play which addressed how to talk to a partner about refusing sex or using a condom (psychomotor domain).

Three. She would have the opportunity to express her fears about how to do this or about the consequences of her STD with someone who could provide emotional support (affective domain).

Four. Ideally the young woman would have the chance to practice skills such as how to talk to her partner or how she plans to take her pills or use a cream for treatment. She would have the chance to practice putting a condom on a penis model (psychomotor domain).

For patient education in STDs, the learning domains might be addressed in the manner described in Box 8.

The education is delivered according to principles of adult learning

Many providers may have experienced education only as it is delivered to children. Thus, it is important that provider training and the design of patient education take into account the principles of adult learning *(see Chapter 6 for details).* The design of teaching sessions and the overall clinic education program can be based on these principles: *respect, immediacy, experience and learning style.*[15]

The education uses multiple channels (visual, auditory, interpersonal)

People learn by using different senses and combinations of senses. It is important to capitalize on this insight by using a variety of media or mutually reinforcing channels to transmit patient education messages *(see Chapter 4).*

A patient education program with sound communication strategies might be illustrated this way: The patient at risk for an STD hears something about STDs on the radio, sees a poster on the way to the clinic, reaches a waiting room that has brochures about STDs and how to use a condom and, while in the interview or exam room, sees a poster with a similar message. Exposure to similar or complementary messages through different channels is thought to be a way to ensure that one of the messages will make sense to a patient and have an impact.[2] Perhaps the message had the right tone or was presented through a medium suitable to the patient. Also, if the message appeared in different settings the impression would be created that there is a general norm regarding sexual behavior, making it more likely that the patient would adopt the new behavior.

Principles of Behavior Change for Prevention and Patient Education

Changing any health behavior is difficult, but changing sexual behavior is especially challenging. Cultural, political and strategic barriers may impede the implementation of effective sexual behavior change strategies. Proven principles of behavior change can provide a valuable reference.[16,17] Even if it is not possible to change the cultural, political, social or economic environment, it may be possible to use some of these principles to motivate change in some of the clients served by STD clinics.

The importance of information

Information is a good starting point in any behavior change effort. Although information-giving alone is rarely sufficient, it can be productive in starting people along the track to behavior change.[18] To be effective, the information must:

- Help individuals understand the risks of engaging in behaviors that will transmit HIV and other STDs, and be accompanied by information about behavioral alternatives such as condom use
- Inform people about what they must do, emphasizing the importance of both new target behaviors as well as behaviors to be avoided as a way to protect their health
- Be easily understood and conceptually relevant for individuals

Risk reduction education

One aspect of risk reduction education is identifying the reasons why individuals are resistant to behavior change and then addressing these barriers. This can be done during the clinic visit through face-to-face behavior change advising reinforced by motivational messages in posters, fliers and other materials.

The problem-posing approach

For behavior change, this problem-posing approach is preferable to simply giving people facts and instructions about what they should do.[14] It means that the provider poses to the individual patient realistic and achievable behavior change options. Patient and provider then establish mutual goals for behavior change that the patient agrees are feasible. Providing options and establishing goals are effective approaches to stimulating behaviors that can be sustained by patients over time.

The role of skill development

In addition to risk behavior education, providers can assist patients in developing concrete skills to make and maintain behavioral changes.[19] Examples include practicing how to talk with a partner about delaying sex during treatment for STDs or using a condom at any time. To simply tell a patient that they must use a condom or insist that their partner use one is inadequate. This information can be read in a brochure. The value of the provider is that they can offer dialogue and feedback as patients rehearse their part in this interaction. Even more effective is providing an opportunity for patients to observe others like themselves demonstrating this skill, and then practicing it and getting immediate feedback.

Relapse in behavior change

Relapse is not unusual or a sign of failure. Individuals have a complex pattern for changing their behavior and then sustaining these changes over time. From time to time, people will experience a relapse and return to risky behaviors that they had been avoiding.

To communicate preventive strategies so that patients anticipate and address the possibility of behavioral relapse is very important. Encouraging patients to plan ahead, asking them to imagine situations where it is difficult to maintain preventive behavior and then giving them suggestions and skills they can use in these situations are ways of helping them maintain the behavior over time.

Patient ownership of behavior change decisions

Make sure patients feel **they** are making the choice to change their behavior: Patient education for safer sex will be more effective if patients are offered even a limited number of choices.[7,20] Alternatively you can ask them to substitute behaviors instead of eliminating them. This is why patients may be more likely to use condoms than to give up sex or give up certain sex practices altogether.

Campaigns that emphasize abstinence alone or sex with only one partner are less likely to succeed than campaigns that also include condom use as an alternative. In those situations where human resources are sufficient and depending on the cultural norms for sexual behavior, more in-depth behavior change advising to suggest alternative forms of sexual expression such as non-penetrative sex can be presented.

The impact of the environment

What we do is affected by where we are and by the people around us.[21] People find it more difficult to refuse alcohol in a bar if they think everyone around them is continuing to drink. Others will find it more difficult to use condoms if they believe they are the only ones using them.

Patient education might attempt to help people avoid environments associated with risky sexual behaviors. Alternatively, health care workers can contribute to the ideas that healthier behavior is acceptable in the society and that a significant number of people have already successfully changed their behavior.

If community leaders change their behavior, others are likely to follow.[22] We often follow the lead of people we respect. More successful behavior change programs use influential community leaders to talk about the behaviors openly and then encourage community members to adopt the behaviors as well.

Adapting Education Messages for Behavior Change

Use available information and formative research results

Educational program design is a combination of scientific and creative efforts. The starting point in the process should include a review of available information on disease and behavioral patterns in the community.[19] Formative research, sometimes called an assessment, is a powerful means to collect additional information, specifically for educational intervention design. Formative research activities vary in their scope depending on how much information is needed and the technical resources available *(see section "The Process of Patient Education").*

Segment the audience for education efforts

Educational approaches to communicating behavior change messages are segmented for distinct target groups.[23] Meaningful segmentation of audiences for behavior change communication in the clinic setting includes analysis of the characteristics of the population served and then identification of key factors that have an impact on communications. These factors may involve gender, age and sexual risk behavior (types of sexual partners, types of sexual contact, number of partners, etc.), but can vary from one clinic setting to another.

Adapt the message to decrease fear and shame

Messages used in patient education should be designed to minimize rather than exacerbate the fear or shame that someone with STDs can feel. Health care workers might need sessions in which they confront and discuss their attitudes about patients with STDs as a way of sensitizing them to what they convey to patients verbally and nonverbally.

Make the message clear

The word "message" is not simply a rephrasing of medical advice or encouragement to adopt a set of new behaviors. Messages for health education must be developed mindful of several issues including medical advice, encouragement of new behaviors and some of the other factors summarized below. With a modest amount of planning and teamwork, involving several members of the clinic team and with input from individuals with communications expertise when available, a set of simple and clear messages directed to different types of patients can be developed.

From the moment patients come into contact with a clinic facility and the members of the health care team, they encounter a series of elements that color their response to the health care setting and the information they receive from individuals in that setting. The patient response to these elements is affected by their emotional and psychological state when they encounter them as well as by the broader societal context. This is not to say that a patient's receptivity to educational messages is beyond the control of STD clinic managers and health care workers. In fact, it is their task to examine clinic services for ways to maximize patient receptivity to educational messages. In this regard, making the services more patient-oriented is important.

Design the tone of the message

Threats and instilling fear may help some individuals become more aware of the need to change behaviors. However, the use of fear has been found to be of limited value.[23] If fear becomes overwhelming for individuals, it can hinder rather than help efforts to change behavior by causing them to be anxious and deny their risk. One symptom of denial is that many patients rationalize their denial by pointing out that they know other people who practice risky behavior but do not have STDs. Some patients adopt a fatalistic attitude saying that some circumstance will end their life anyway, and so why should they worry.

If health workers do use fear to convey an STD prevention message, great care must be taken to balance the level of fear so that patients are not pushed into denial.[24] Messages should give people realistic and effective alternatives and encourage them to take positive action in response to the threat conveyed in a fear message.

An example that combines a threat or fear message with a message that conveys that the patient has control is as follows: If you have sex with many partners, you will get an STD and maybe even AIDS. If you have sex with fewer partners and use a condom each time, you are unlikely to get an STD, and you can reduce your risk of HIV infection.

Design messages that stress positive results of healthy behavior

In different cultural settings, there are many reasons why people are reluctant to use condoms. Some complain they are uncomfortable, reduce pleasure and even cause disease. Highlighting some of the pleasurable aspects of condoms while emphasizing the health risks of unprotected intercourse and other negative consequences can be useful. For example, among people who have a strong motivation to protect the health of their family, condom use with casual partners can seem like a reasonable alternative to facing the risk of infertility or STD infections in the newborn. Among sex workers, however, it may be more effective to suggest that these illnesses can have a negative effect on their income and that they can cause serious health problems for their children should they become pregnant.

Make the target behavior easy and appealing

Whenever possible, new behaviors should be explained step-by-step in order to give people the confidence that they can perform them on their own.[21] Telling people that using a condom is easy can have negative consequences when the patient experience is otherwise. Also, telling STD patients to stop having casual partners may be unrealistic. It may be more effective to ask them to use condoms instead.

Ideally, people should have the opportunity to plan and rehearse how they will behave in challenging situations. For this reason, teaching condom use skills is an essential part of STD patient education. Any opportunity to highlight the appealing aspects of the desired behavior and give people practical hints on how to negotiate condom use should be fully utilized.

Practice sessions could include:

- How to put on and take off a condom
- How to use nonverbal techniques (e.g., handing a condom to a partner) for encouraging condom use or engaging in safer sex activities
- How to talk about safer sex and condom use

For example, if a clinic education program objective is to teach sex workers that they should only accept sex with clients who are willing to use a condom, then they may want to rehearse some phrases. This will increase the probability that they will actually use these negotiation skills when talking with their clients. If this is done in a group, the sex workers themselves can recommend ways that they encourage condom use.

Another way to make people feel capable of changing their behavior is to show them examples of people like themselves who have already changed. This is called modeling the desired behavior, and it can be very effective in getting people to feel comfortable and capable of trying new behaviors like condom use or reducing their number of partners. Posters and audiotaped or videotaped dramas depict couples talking about using condoms or sex workers negotiating condom use with clients may help people feel supported in adopting these behaviors as well.[25]

Limit the number of messages

A common problem with patient education is that health care workers often sense that they have one opportunity to give someone information. Therefore, they try to cover as many behavior change topics as they can in a limited amount of time. But communicating too many different messages can leave a patient overwhelmed and confused. Health care workers should use the concepts discussed in this chapter to assess which three or four behavior change messages are the key ones, and discuss with the patient during their brief meeting.

Box 9

Elements of Behavior Change Communication

- Develop messages that are based on existing information and on formative research.
- Segment the audiences.
- Limit the number of messages and make them clear, not fear-based. Emphasize positive results of behavior changes, and make adopting new behaviors sound easy and appealing.
- Suggest behaviors that are realistic and achievable.
- Provide skills to initiate and maintain behavior change.
- Create supportive social norms, such as for condom use.
- Be prepared and prepare patients for relapses.

The Process of Patient Education

Make an assessment

Assessment, sometimes called formative research, begins the process of designing an education program. The assessment phase of patient education in STDs should address both the community and individual levels. Managers need to know what else is being done about STDs in the community, other sources of information to which patients have access and in what ways their clinics can contribute the most to meeting patient needs.

The assessment should answer the question of who needs what as defined by whom.[14] This question might need to be asked repeatedly. To learn this from patients is quite useful. For example, if a group of young women were asked what they need to know about STDs, their answers might be quite different than what the clinic nurse might define as their learning needs. On a community level, conducting ethnographic research about STDs might be the most useful first step, whereas on an individual level letting patients ask

questions or describe what they think causes and cures STDs is a good starting point.[26] *(See Chapter 13.)*

On the individual level, assessment should address not only the content of the education program but also the method.[27] Individual styles and the need to address the different domains of learning are discussed elsewhere in this chapter. The purpose of the assessment phase is to gather the information needed to determine the learning style and critical content of the education program. The assessment can be done using key informant interviews, focus groups, individual interviews, and knowledge, attitude, behavior and practice (KABP) studies. The answers to the assessment questions form the basis for the design of educational materials, audiotapes and content for health talks or advising sessions, and help the provider know what a patient from the local community is likely to believe about STDs. This helps the provider to use local terminology, correct misconceptions and redirect health-seeking behaviors.

Questions that need to be addressed by the assessment used to design an educational program include the following:[28]

- What are the target behaviors of the patients related to STDs that need to be changed?
- What are the patient abilities and constraints in making the changes?
- What adverse effects (e.g., a partner's embarrassment) would develop for others if the behavior changes occurred?
- What environmental factors facilitate or prevent change?
- What consequences does the behavior have for the patient and for others he or she interacts with in the community?
- What satisfactions continue for the patient if the problem behavior continues?

Box 10

How to Confuse a Patient and Get Nowhere

Nurse: Well, Karima, it seems that you have what is called gonorrhea. It is a bacterial infection that is transmitted sexually and can lead to complications such as pelvic inflammatory disease.

Karima: *(She says nothing and looks down. It's an oriental disease that is going to inflame me for life so I can't have sex, she thinks.)*

Nurse: You must tell your husband to wear a condom so he does not give it to you again. He is infectious until he is treated and he might have urethritis. He must come to be treated as well.

Karima: *(Sits with her head down. My husband thinks I run around when he goes out of town already, she thinks, and we still do not have children. If he wears one of those things I think she's talking about we'll never have kids and worst of all he'll think I'm running around. I know he got this from one of those prostitutes in town. He'll never come to this clinic for medicine...then his sister, the nurse out front, would know what he's doing to me.)*

Nurse: *(Pulling out a syringe and looking away)* Any questions?

Karima: *(Thinking of what she must say, but before she can say it...)*

Nurse: Can you get up here on the table so I can give you a shot? Now I'm going to give you pills too. You need to take one every four hours, you can remember that, can't you, because if you don't you won't get better and it will go to your tubes and ovaries and you'll have to go to the hospital....don't take the pills with too much food or the medicine won't get absorbed and if you get a rash, which these pills cause in people who are allergic, you should let us know.....

(finishing the injection)

Now go on home and do what I told you...you talk to your husband, ok?

Karima: *(Walks out of the room to go home and forgets to stop at the pharmacy.)*

- What satisfactions would occur if the behavior were changed?
- Is the patient capable of undertaking the recommendations for behavior change?

Assessment also needs to address questions such as these:

- What do patients see as the types of STDs and what terms do they use to describe them?
- What do patients think causes each STD syndrome and how do they think it is transmitted?
- What do patients think prevents STDs?
- What do patients currently do about STDs and at what point during an STD episode?
- What do patients think cures an STD?

On an individual level the provider should also assess whether the patient is ready to learn at a given point in time. The patient who presents to the clinic with acute pain due to pelvic inflammatory disease (PID), for example, is not a candidate at that point in time for a discussion about her sexual behavior or the intricacies of persuading her partner to use a condom. This should be addressed at a time when she is not in pain and can participate fully. Also, a young woman might not be ready to learn about STD complications if she just experienced her first intercourse and is very upset about mild vaginitis.

Establish priorities

When time with a patient is very limited, as is usually the case, it is important that the provider make a sound decision about what should be the priority issues to address. Too often providers feel compelled to deliver a long list of facts covering everything they would like patients to master about STDs. This window of opportunity should instead be used to find out the information need of a particular patient. Then the provider should choose the three or four most relevant topics to discuss with him or her. The antenatal clinic client with syphilis needs to know more about her treatment, the risks to her infant and the importance of returning for follow-up than she does about vaginal discharge and its causes. On the other hand, a man coming to the clinic with urethritis needs to know less about ophthalmia neonatorum as a consequence of urethritis and more about what lubricants it is recommended to use with a condom and how to complete his course of medication and partner treatment.

Identify long- and short-term objectives

The identification of long- and short-term objectives of patient education is part of the planning process. The young woman who just had her first intercourse certainly has a need to know more about STDs and HIV. But the short-term objective of her patient education is that she understand that the vaginitis she developed is not gonorrhea or chlamydial infection and can be easily treated. The long-term objective is that she understand her risk of contracting other STDs, their relationship to HIV/AIDS and the means of preventing them.

Identify barriers to learning

Prior to initiating efforts at patient education, the provider must identify barriers to learning, be they on the individual or group level. Common barriers in the area of STDs include a cultural taboo on the discussion of sexual issues or functions, a taboo against speaking of sexual matters with someone of the opposite sex, beliefs that define causes as magical or supernatural and other traditional beliefs that do not match or may contradict biomedically based explanations.

Assess the learning environment

It is critical to ensure that the environment is conducive to the educational method being employed. For example, the waiting room is appropriate for a presentation in which patients need not reveal very much personal information, whereas the interview room is not well suited to an interactive presentation or group session.

Evaluate client progress

In all matters of health care, there is usually an advantage to continuity of care. When possible, it can be of tremendous importance that the patient return to see the same provider or participate in a session led by this individual. This allows the provider to set short- and long-term objectives and move the patient along the continuum at a pace suitable to the learner. When this is not feasible, as is often the case, the provider delivering an educational message or program must assess the client's progress in learning about STDs and in adopting risk reduction behaviors.

Approaches to Patient Education

There are many different methods that can be used to deliver education to patients in the clinic setting. It is useful to determine which methods will be used by asking basic who, when, where and what questions, as outlined below.

Determining the appropriate providers

All staff members can contribute to a patient education program. Some health care workers contribute simply by being empathetic, respectful, and reassuring, which preserves patient dignity and reduces the fear and shame that a patient may feel. Others might focus on giving more complex technical information in an understandable and non-threatening fashion, and in a limited time period.

A clinic manager should examine the entire staff, both professionals and non-professionals, to determine their roles in providing patient education. The preparation of the personnel in a clinic should determine which provider can best address which aspect of patient education. The basic facts about STDs can be taught by several levels of health care workers. But, the finer points of counseling a woman about how to encourage a hostile husband to use a condom requires that a provider be a trained counselor or at least have learned techniques suitable to this sort of intervention. The person most suited to advise regarding the meaning of certain symptoms or complications would be the most medically trained person available.

An effective means of reinforcing health education messages is having the front desk registration staff, security guard or cleaning person talk about condoms in a positive light, as long as they are willing and comfortable interacting with patients. In general, it is advisable to develop an approach that utilizes many persons on the team. As a result, the different points of opportunity for education during the patient's clinic visit are taken advantage of and messages are conveyed repeatedly.

Determining the points of opportunity

Managers should be sure that the design of patient education is based on the concept that it is useful for messages to be transmitted at numerous times during the patient's visit to the clinic. By analyzing the steps patients go through when they come for services, such as registering, waiting and being examined, one can address the various points of opportunity for education.

The method should be suited to the point of opportunity. To ensure this, it is helpful to analyze a given clinic encounter and how it is composed of many different action intervals at various locations within the clinic. For example, a patient enters most clinics through a waiting area. Then there might be an intake area or a place where vital signs are checked. Usually, the patient then returns again to the waiting area. In some clinics, patients subsequently are sent to the lab. Next, they are seen in an examining room and, after that, sent to a clinic pharmacy or one in the community. The analysis of a patient visit would lead one to conclude, for example, that counseling should not occur in the intake area, since counseling cannot be conducted as effectively in hearing distance of other patients as it can be in privacy.

In other words, interventions can be timed to reach patients during many different but appropriate moments during their clinic encounter. Different intervals may be associated with different levels of patient receptivity to education. For example, although diagnosed with an STD for the second or third time by the same practitioner, a male patient may be so relieved after being told of his negative HIV test results that he does not show an interest in behavior change advice. Alternatively, a woman may be so concerned with supervising the three children she has brought with her and feel anxious about the implications of an STD infection that she is unable to focus on the posters or printed information she encounters in the waiting area.

At each point during the patient's visit there are opportunities for patient education that might take the form of playing an audio cassette dramatizing some aspect of condom use, having a poster in a place where it can be looked at for a period of time, reading materials or setting up an interaction between provider and patient. The examples in Box 11 illustrate making full use of clinic opportunities for patient education.

Box 11

The Patient Point of View: Joseph Makes the Clinic Scene

The waiting room: 12:00. In line.

Gee this discharge burns. Here's the clinic.
Nowhere to sit as usual.
And the usual 15 people in front of me....yawn.
I hate this. I need to get to work.
Music! What's that TV on the wall?
There's a guy who looks just like me. He's telling a cute girl that she needs to go to bed with him.
Oh no, don't remind me of why I'm here.
Whoops, what is she doing? She's saying no and holding up a condom. Sina tried that last week.
Maybe I should have listened.

The registration desk. Signing up. 12:45

The clerk is speaking in a very soft tone.
Where's the usual screech?? What's that pile of brochures doing there?
There are pictures of men and women and condoms again, like in the video.
She wants to know why I'm here and whoa,
I get to look at pictures and choose from a list...no one can see....

The laboratory. More pictures. 1:15

Needles, needles, everywhere, but wait....there's a picture of what I have....now I know...it's urethritis, whatever that is....here's the lab tech now....he's telling me what this is all about...whoops, there's another condom...they're everywhere....

The doctor. Finally. 2:30

Here's the real thing, medicine, and he's telling me what I have and why I have it.....I even asked a question, quick, but that's ok.
He tells me to practice putting this condom on this wooden thing....wish I were that big....wow, I did it.
I don't know about that, but I don't know about this....sure burns a lot....whoa, here's a whole handful of condoms....maybe I'll have to try some....just once....

Patient education content and focus differ according to type of clinic site. The content of what is offered in patient education must be tailored to the type of clinic service for which the educational materials or provider messages are designed. In addition to clinic sites designed for STD and HIV/AIDS patients, primary care, family planning, antenatal, maternal and child health, and obstetrics and gynecology clinics can all better serve patients by including STD patient education.

The STD patient education program must be designed taking into consideration the priorities, values and level of understanding of the clientele of each clinic. For example, in a typical family planning clinic, the priority of the patients and health care workers is on encouraging patients to select and consistently use a contraceptive method that is right for them. However, it is important to note that the woman seeking a family planning method might have a husband who is HIV-infected or who has an STD. She could also benefit from information and discussion about the signs and symptoms, risks and ways to prevent STDs. The same holds true for clients in the other clinics, especially antenatal clinics, if one considers the risks of congenital syphilis and the effects of chlamydial infection and gonorrhea on infants *(see Chapter 9).* Since the mind-set of the patients might not be on learning about STDs, the health care worker must take this into account and introduce the topic sensitively.

For a patient with an STD, it is expected that STD education will take priority over other topics. Although patients may be uncomfortable talking about sexual behavior, they are likely to understand why this is a topic of discussion. Instructions and messages for these patients will be more detailed and be given greater priority than in the clinic situations mentioned above.

The response of health personnel to patients with an STD diagnosis might differ according to the type of clinical service in which they work. For example, in a primary clinic, a nurse might not be accustomed to dealing with young men with penile discharge. Her reaction to this may be awkward or she may express some discomfort or a hypercritical attitude. This can raise the young man's anxiety level and compromise his confidence in the nurse, her message and the treatment she offers.

There are logistical and resource challenges clinic managers must face. The clinic manager is challenged to help health care workers modify the clinic configuration to facilitate the implementation of the principles discussed in this chapter: providing privacy and confidentiality; establishing the ideal moments during the visit for different aspects of patient education; understanding the value of using multiple channels; and knowing how to take advantage of every opportunity.

The physical circumstances in clinic settings may dictate the type and amount of patient education. A patient flow of 15 or 20 people per hour makes it unrealistic to expect more than basic patient education, including time-efficient behavior change advising, to occur during the exam portion of the visit.

If a certain degree of privacy and confidentiality can be assured, face-to-face communication between patient and health care worker can address the specific obstacles and motivation for behavior change. With large groups of people in waiting areas, it may be difficult to transmit personal or sensitive information. But a waiting area may be the ideal setting for posters, audio and/or video, flip charts to reinforce behavior change, either before or after a confidential face-to-face interaction with a provider.

Determining content and educational techniques

The range of content is determined by the patient population–principally the reasons for their visits as well as their individual and collective levels of knowledge. Boxes 1 and 8 of this chapter outline major components of information that most patients need. The final step in planning is to determine the best educational approach and specific content to use at the different points of opportunity that arise during the clinic visit.

Summarized below and discussed in detail in Chapter 4 are some of the most commonly used techniques for delivering effective education in the clinic setting.

Interpersonal communication: The quality and tone of communication between provider and patient determines its effectiveness. When patients feel comfortable in a clinic environment, they will be more interested in behavior change information, less ashamed of having an STD infection and perhaps more inclined to ask questions. This makes it much easier to deliver health education information that meets their individual needs. Health care workers can examine the ways they communicate with patients both verbally and nonverbally in order to enhance educational impact.

As tools for self-learning, *posters* are another approach to patient education in the waiting area of a clinic. Content can include basic STD prevention messages or information on how STDs are and are not transmitted, if this is appropriate in the local culture. Also, posters that reassure patients that confidentiality is respected and protected can be as important as STD prevention posters in supporting health education in the clinic setting.

Videotapes or audiotapes also can be used in the waiting area, as can pamphlets or short story books that use cartoons to describe situations patients can identify with. The content of these materials will vary according to the information needs of the population and the acceptability of printed material discussing or illustrating aspects of sexuality. This invites the patient to refer to the materials later, reinforcing the messages conveyed during the clinic encounter. For example, small pocket-sized formats and simple unprovocative covers can be used for brochures for adolescents.

Developing patient education materials is an important process that should be executed systematically. The technical expertise for pre-testing educational materials is frequently available on the local level in most countries of the world. Ensuring that the development of educational materials goes through the necessary steps can improve the quality and effectiveness of educational materials for the clinic setting.

Other approaches to patient education such as *presentations or talks* using an interactive approach instead of a didactic one, *group discussions and role plays* can also be effective. These require leadership by an informed and skilled provider. Group discussions are useful because individuals can gain insight from the input of others who have similar problems. These groups can also transmit knowledge and provide emotional support. Role plays are excellent skill-building tools, especially in the area of interpersonal communications. During role plays, patients have the opportunity to practice what the provider has suggested that they do. They can get immediate feedback and build confidence in a non-threatening situation, enhancing their potential for performing well in real-life situations. Role plays are useful in helping patients explain to their partner that they have an STD, in requesting that their partner use a condom or that they use one; also, in requesting that their partner agree to delaying intercourse for as long as the patient has an STD or until the partner can get treated as well.

Evaluating Patient Education at the Clinic Site

There are a variety of techniques for evaluating the success of patient education. The most powerful techniques are ones that measure actual behavior change, since that is the goal. A pre- and post-test could easily assess knowledge gain. But it is possible that the patient with a perfect knowledge score might return with an STD because they were never convinced about or never comfortable with condom use.

Other techniques such as mystery patients (where a health care provider poses as a patient in order to observe a clinician's performance) and in-clinic observations have been used in some cases. There has been much work but no final definitive recommendations about the perfect technique for evaluating the success

Box 12

Opportunities for Patient Education

Clinic waiting room

Health/peer educators, local theater groups or clinic staff can provide:

- Media or short dramatic presentations
- Small group discussions
- Informal health educator presentations
- Formal health talks
- Videos, audiotapes, posters, comic books and/or brochures
- Condom demonstrations where culturally acceptable

Exam/interview room

A doctor or nurse can provide:

- Key questions and answers
- Behavior change advising
- Empathy and reassurance
- Condoms and condom practice

Laboratory

A laboratory technician can provide:

- Posters, brochures and condoms

Pharmacy/dispensary

A pharmacist or clerk can provide:

- Posters, brochures and condoms
- Medication instructions

of patient education interventions. Clinic managers have the responsibility of choosing the most cost-effective, valid and reliable method of evaluating their patient education efforts *(see Chapter 14)*. Being clear about educational objectives and providing the means to achieve competency in delivering patient education are the first steps.

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CHAPTER 11

Partner Management

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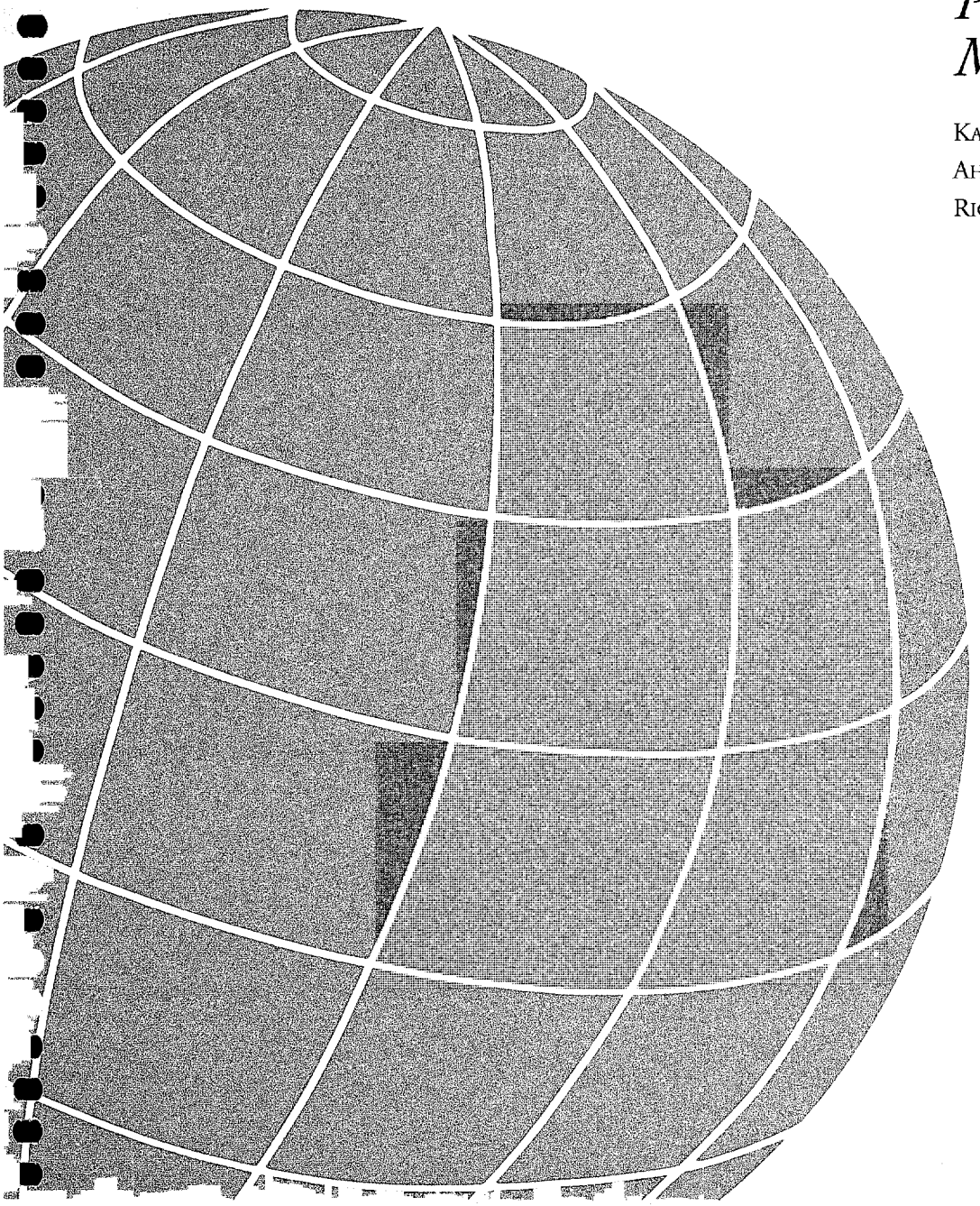

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Partner Management

INTRODUCTION

Partner notification is essential to interrupting the chain of STD transmission. It also offers an opportunity to provide focused STD/HIV education. However, it is one of many strategies, not the sole strategy, in a comprehensive STD/HIV prevention program.

BACKGROUND

Notification of exposure to STDs, including HIV, can be carried out by the infected person (the index patient) or by a health care provider. The program must be voluntary and the infected individual must choose to be involved. Other STD/HIV intervention services such as counseling, testing, and medical and social services should always be offered in conjunction with partner notification.

TYPES OF PARTNER NOTIFICATION

- Patient referral
- Provider referral
- Combination referral

PRINCIPLES OF PARTNER NOTIFICATION

- Voluntary participation
- Confidentiality
- Accessibility
- Quality assurance
- Do no harm

PATIENT EDUCATION INFORMATION

Basic information should be communicated to the index patient regardless of who does the notification. This should include such things as how STDs are transmitted and the implications of infection.

PARTNER NOTIFICATION ACTIVITIES

Preventing STD/HIV transmission and averting complications from infection are the goals of partner notification. Numerous educational and other activities (outlined in this section) should be included in partner notification programs.

APPROPRIATE SETTINGS FOR PARTNER NOTIFICATION

Any health care facility—from a primary health care clinic to a hospital outpatient department—can serve as a suitable setting for partner notification. Informal providers such as pharmacists and traditional healers can also be involved in educating patients about partner referral. Referral cards are an efficient way to expedite diagnosis and treatment (examples are provided).

SETTING PRIORITIES FOR PARTNER NOTIFICATION

Primary health care clinics in most countries have limited resources. If partner notification can identify core groups—partners most likely to transmit infection to others—the disease control impact will be greater.

CONCLUSION

Since partner notification must occur in a unique cultural and medical environment, no single program can be applied universally. Cost is a factor in most countries, and some components of a program can be implemented inexpensively, such as with index patients using referral cards. However, the cost of establishing a provider referral system may be too high for most programs.

INTRODUCTION

The objectives of an STD/HIV prevention and control program are to prevent and interrupt disease transmission and prevent the development of STD complications. These objectives cannot be achieved merely by providing treatment for individuals presenting with signs or symptoms of STDs. Other public health measures are required to identify susceptible populations.

One important public health intervention to interrupt the chain of STD transmission is partner notification, in which the partners of those identified as having STD are located, informed of their potential risk of infection, and offered medical and counseling services. Partner notification also offers an opportunity to provide focused STD/HIV education to individuals who are by definition at highest risk of infection. Counseling and focused education may be a means of achieving behavior modification to reduce high-risk sexual behavior.

Partner notification may identify partners who are asymptomatic or who have minimal symptoms and would not otherwise present for medical treatment. For example, STDs have severe, long-term and potentially life-threatening complications in women, including infertility and ectopic pregnancy. Yet many women with STDs have no signs or symptoms of disease. These women may not receive curative treatment unless they are screened for asymptomatic infection. Partner notification is often the only way to identify these women at risk of infection and to prevent damaging STD complications.

Partner notification should be considered in any STD prevention program and in any situation where STD clinical services are provided. However, it is only one of many activities needed for effective STD prevention. Partner notification should not be a program's sole prevention strategy and should only be implemented within a comprehensive STD/HIV prevention program.

BACKGROUND

Efforts to notify people who may have been exposed to STDs, including HIV, can be carried out either by the infected person (the index patient) or by a health-care provider (previously known as contact tracing). In traditional STD control programs, the primary reason to notify the partners of index patients is to ensure that at-risk individuals have the opportunity to receive therapeutic or preventive treatment before serious disease complications develop. In addition, by treating exposed individuals early in the course of a disease, providers can reduce the length of the period of communicability and break the chain of disease transmission.

In contrast, the primary purpose of HIV partner notification is to stop the spread of HIV by providing individual risk reduction education to those who are HIV-positive and to those who, although uninfected, are at risk of infection. Health-care providers or the index patients themselves counsel partners of HIV-infected individuals about safer sexual behaviors and about the availability of HIV testing. This process also allows health-care providers to offer HIV-infected individuals medical evaluation and support services earlier in the course of infection. If the partners choose to be tested and test positive for HIV, they are told how to protect their health and can be informed about the medical and support services available to them.

Providing the names of sex partners (or needle-sharing partners) during the interview should always be voluntary. Ensuring confidentiality—protecting the patient's identity and the privacy of named partners—is crucial to securing the cooperation of patients. Any process designed to identify partners that is coercive to index patients or partners, does not ensure the confidentiality of its participants, or does not depend on the voluntary participation of the patients should not be called a "partner notification" program.

In the United States as well as several other countries, partner notification has been performed almost entirely by trained health department professionals, known in some programs as disease intervention specialists (or DIS). In most programs, patients are offered the option of notifying their partners and referring them for assessment and treatment. Many patients wish to remain anonymous, however, and prefer having health department staff inform their partners.

STD and HIV partner notification programs are, by definition, voluntary since the infected individuals must choose to be involved in the process. In addition, partner notification should always be offered in conjunction with other STD/HIV intervention services, such as counseling, testing, and medical and social services.

TYPES OF PARTNER NOTIFICATION

Partner notification can be carried out through two distinct strategies—patient referral or provider referral—or through a combination of both strategies.

PATIENT REFERRAL

Through patient referral, an index patient is encouraged to notify partners of their potential exposure to infection. The health-care provider is not directly involved in notification. Providers should, however, offer counseling to the index patient about the importance of partner treatment and encourage index patients to bring their partners to the clinic for services.

The success of patient referral is absolutely dependent on index patient and partner motivation and the quality and appropriateness of counseling received by the index patient. Patient referral is often the most acceptable form of partner notification because it does not require additional resources or personnel, and because patients do not have to identify partners by name to a health-care provider.

PROVIDER REFERRAL

In provider referral, a health worker locates partners identified by the index patient and offers them treatment. In some settings, outreach or community health workers may be able to ask partners to come into a clinic to see a health worker without having to explain (or even know) that the visit arises from partner notification for an STD.

Patients' concerns about confidentiality may limit the disclosure of information identifying partners. Index patients should be counseled and assured that confidentiality will be maintained and that their own clinical treatment will not be jeopardized by their participation in this process.

COMBINATION REFERRAL

In practice, only clinics that specialize in STD services are likely to have active provider referral programs. However, partner notification as practiced in these settings usually results from a combination of patient and provider referral. With combination referral, index patients may name some partners but notify other partners themselves. Sometimes index patients are given an interval of time to bring partners to the clinic for follow-up before providers begin to notify named partners. Often clinics offer provider referral for syphilis and patient referral for all other STDs.

PRINCIPLES OF PARTNER NOTIFICATION

Regardless of the type of partner notification approach used in a given program, the following five principles must be followed:

VOLUNTARY PARTICIPATION

Disclosing the names or identity of partners should always be voluntary. STD/HIV counseling, testing and referral services should be available to index patients regardless of whether or not they choose to participate in partner notification. Occasionally a person who is infected with HIV consistently refuses to notify his or her partner or to identify these partners to a health worker. If the health worker knows the person's partners, he or she may feel obligated to inform them. However, such disclosure is illegal in some countries. This difficult ethical question needs to be addressed in the local context of each situation. It is always better to continue talking to the patient to obtain voluntary cooperation. Partner referral should not be a condition for receiving treatment. Experience has shown that such coercive measures can deter patients from seeking care or even encourage them to bring in any person whether they are a sexual partner or not.

Confidentiality

All records must be kept strictly confidential. Partners' names must be used only for field investigation and notification purposes. In no instance should partners be told the name or identity of the index patient, the date or period of exposure, or the infection status of the index patient.

Confidentiality of STD/HIV records, particularly those relating to partner notification, should be legally protected if possible. Lack of confidentiality will be a barrier to implementing partner notification programs. Unless index patients and communities at risk perceive benefit from the STD/HIV services, including partner notification, they may be reluctant to come forward for treatment and may turn instead to other possibly inadequate sources of care.

When confidentiality of records cannot be ensured, health providers should destroy written records relating to the index case as well as locating information regarding partners after partner notification has been initiated.

Accessibility

Program managers should ensure that referred partners have access to STD care and preventive services.

Quality Assurance

Program managers should routinely evaluate the performance of counselors and other program personnel to ensure that high-quality services are being delivered. They should also establish quality assurance and training guidelines to be followed by all professionals engaged in the partner notification process. Whatever partner notification model is selected, health providers must ensure that procedures for managing patient records are well-developed, detailed and confidential. In addition, all participating personnel should have completed a structured training course covering STD/HIV infection control, interviewing skills, partner notification techniques and confidentiality provisions.

Staff training for partner notification should include the following elements:

- Basic counseling and education skills, including crisis intervention, relationship counseling and skills in discussing sexual behavior
- The natural history of STD/HIV
- The epidemiology of STD/HIV among specific populations within geographic areas and local communities, including sexual transmission, asymptomatic carriage and consequences of non-treatment
- The psychosocial implications of STD/HIV infection
- Index patient interviewing skills and techniques.
- Risk-reduction issues
- Referral resources
- Record keeping
- Evaluation

Do No Harm

Program managers should ensure that clinical care providers consider the possible social consequences of partner referral for each individual patient. For example, in Nairobi, Kenya, some women with STDs may be at risk of violence from their partners when they request their attendance at a clinic.[1]

PATIENT EDUCATION INFORMATION

Regardless of who carries out the notification, certain basic information should be communicated to the index patient. Education should include information about:

- The modes of STD including HIV transmission
- The disease process
- The possibility that infected partners may be completely asymptomatic
- The possibility of reinfection if partners are not adequately treated
- Complications that could occur if partners are not adequately treated
- Recommendations for modifying patient and partner behavior
- The location of STD/HIV treatment, counseling and testing services
- Referral to support groups, HIV testing facilities and other medical facilities if available

PARTNER NOTIFICATION ACTIVITIES

The goals of STD/HIV partner notification programs are to prevent STD/HIV transmission and avert complications of STD infection. To meet these objectives, programs should include the following activities:

- Educating STD/HIV patients about how they can prevent transmission of STDs to others
- Referring patients for medical evaluation when appropriate
- Locating sex and/or needle-sharing partners identified by the patient and notifying them of their risk of infection
- Treating partners of STD patients epidemiologically; that is, treating the partner for the same STD syndromes as the index patient *(see Table 1)*
- Educating uninfected partners about how to reduce their risk of exposure to STDs/HIV
- Referring partners for medical evaluation and further counseling when appropriate

Table 1
RECOMMENDED MANAGEMENT OF PARTNERS

Diagnosis	Partner Management	Interval of Look Back*
Urethritis in men	gonorrhea chlamydia	1 month
Genital Ulcers in men and women	syphilis chancroid	3 months
Pelvic inflammatory disease	gonorrhea chlamydia	1 month
Vaginal discharge	gonorrhea (?) chlamydia (?) trichomoniasis (?)	1 month
Gonococcal ophthalmia neonatorum	gonorrhea and chlamydia in both parents	—

**Likely period of infectiousness prior to diagnosis*

In most settings all pathogens common to the STD syndromes are not readily diagnosed. For example, identification of *Chlamydia trachomatis* and *Hemophilus ducreyi* is not available in the vast majority of STD patient encounters. Consequently, if all specific etiologic agents cannot be excluded and confirmed for each syndrome, then therapy in the referred partner as well as for the index patient should be syndromic.

APPROPRIATE SETTINGS FOR PARTNER NOTIFICATION

Few countries have well-developed public health infrastructures to carry out provider referral activities. In general, where these services exist, provider referral

is available only within specialized STD clinics. However, patient referral can and should be a part of comprehensive patient care for any STD patient, regardless of where treatment is delivered.

Partner notification can be made available from any health facility, including primary health-care clinics, maternal and child health clinics, family planning clinics, outpatient departments of hospitals, workplace health centers and private clinicians' offices. STD care is also available in many countries in the informal sector through pharmacists, traditional healers and street vendors. STD programs should involve these informal providers in educating patients about the need for partner referral.

Partner Notification in Clinic Settings

At a minimum, health-care providers seeing STD patients should educate patients about the importance of informing partners of their need for treatment. The index patient would then carry out partner notification, informing partners and advising them of their need for treatment. Patient referral may be enhanced by the use of special cards given to the patient to pass on to his/her other sex partners. These cards can help clinicians provide prompt diagnosis and treatment when partners present to the clinic for care *(See example cards, Figures 1 to 3).*

These referral cards can be designed to allow a clinic or program to estimate the percentage of index patients who actually refer partners. In Rwanda, for example, partner referral slips linked by a code number to the index patient were used to estimate that partners of 45 percent of index patients came in for evaluation. They were also able to determine that pregnant index patients were the most successful in referring partners.[2]

In many countries, cultural barriers to the development of partner notification programs may exist. For example, notifying the male spouse of an infected female patient might cause social disruption to the family or even physical harm to the wife. Strong community opposition to these programs may impede their effectiveness. In some countries, for example, homosexual men have perceived partner notification for HIV as discriminatory and have been reluctant to cooperate with health-care workers. STD/HIV programs that maintain good relationships with their patients and communities at risk will achieve greater patient compliance and ultimately greater public health success.

Figure 1

Partner Referral Card Used in Cameroon in Pre-packaged Prevention and Therapy Kit for Urethritis Mstop

My dear,

After a medical examination, the doctor found out that I was infected with a sexually transmitted disease (STD).

You also run the risk of being infected.

I advise you to go to a health centre for consultation.

See you soon.

Figure 2

PARTNER REFERRAL SLIP USED IN ZAMBIAN ANTENATAL CLINICS FOR WOMEN WITH REACTIVE SYPHILIS SEROLOGY

Partner Treatment Slip

Index Number: _____

Name of Facility: _____
Address: _____

Please provide the bearer of this slip with the following treatment.

Non-Penicillin Allergic	Benzathine Penicillin G 2.4 MU IM. a) Single dose or b) 1 dose a week for 3 weeks Circle the treatment administered.
Penicillin Allergic	a) Doxycycline 100 mg twice daily for 15 days or b) Tetracycline 500 mg QID for 15 days Circle the treatment administered.
Condoms Provided	O Yes O How Many _____ O No

Medical Personnel Signature: _____
Date: _____

Please return this slip to the above address, or ask the bearer to return this slip to the above facility through the post or their partner.

** Recommended dosage for primary, secondary and latent syphillis: Benzathine Benzylpenicillin 2.4 million IU IM in a single session. (WHO Drug information, vol. 6, no. 1, 1992).*

Table 2

STD PREVALENCE IN THREE POPULATIONS OF WOMEN IN BLANTYRE, MALAWI[3]

	Sex Workers	Symptomatic Women	Contacts to Men with Urethritis
Gonorrhea	29%	24%	31%
Trichomoniasis	27%	36%	27%

In most settings where referral patterns have been evaluated, women identified with STDs are more likely to refer their male partners for treatment than are male STD patients. Nonetheless, all the female partners, including the spouse of the male STD patient, should be referred for evaluation and treatment if possible. The referral of female partners of male index patients may be one of the only ways to identify asymptomatic STDs in women. In Malawi, for example, asymptomatic contacts of men with urethritis had STD prevalence rates similar to commercial sex workers and symptomatic women *(see Table 2)*.[3]

In some instances, trained outreach workers may carry out provider referral, interviewing patients to identify partners and obtain locating information. In Zimbabwe and Haiti a combination of patient and provider referral was used involving the already existing community outreach worker *(see Box 1)*.[4,5] At the Wachira Venereal Disease clinic in Bangkok, Thailand, social workers are able to reach 70 to 80 percent of the wives of male STD patients through combined patient and health provider referral.[6]

SETTING PRIORITIES FOR PARTNER NOTIFICATION

In most countries primary health-care clinics and specialized STD clinics have limited resources for STD management including provider referral systems. The STD program manager must consider a number of possible factors that will influence the policies and priorities of a partner referral system.

Box 1

Partner Notification Outreach in Zimbabwe

In a pilot study conducted by STD program staff in a peri-urban area outside of Harare, Zimbabwe, outreach workers referred to as health assistants were trained to perform partner notification. As part of their daily routine, these health assistants visit homes and business premises to help control rodents, mosquitoes and other insects; inspect premises where food is prepared; provide health education; and investigate infectious diseases. This cadre of health assistants (now called extension health workers) is known and accepted by the community.

Special forms were developed for recording partner notification information *(see Figure 3)*. All patients with STD were asked to name all partners and to provide addresses and locating information. If a patient was reluctant or unable to name partners, however, s/he was not coerced in any way.

Clinic staff educated patients about the importance of notifying partners. Names and locating information were shared with health assistants. However, partners were not sought for a period of time—most often seven working days—to allow the index patient an opportunity to carry out the notification. Index patients were given one or more contact cards to pass on to partners and told that if the cards were not returned to the clinic within seven days, health workers would visit the addresses shown on the back of the card. After the contact period passed, the health assistants notified partners who had not presented for care.

During the first five months of the pilot study, almost 20 percent of the 1,723 contact cards issued were returned by partners of index patients seeking treatment. Another 367 partners were notified, and at least 202 sought treatment. The only additional expense to the program was the cost of printing the contact cards. As a result of the pilot study findings, the partner notification program has become a routine service in Zimbabwe.

Figure 3

Contact Tracing Card Used in Zimbabwe: Front Sheet

File Copy

No. _____

_____

(name of health institution)

Contact Name _____ **M F**

Address _____

Area _____

Introducer Name (index) _____ **M F**

Code 1 2 3 4 5
6 7 8 9

Issuing Clinic _____

Date _____

Figure 3

Reverse Side of Contact Tracing Card Used in Zimbabwe

Outpatient Clinic Card

When this card is brought to your clinic, please confirm that the name and address of the person bringing it corresponds with the name and address on the other side.

Then complete the date of first attendance and the name of the clinic attended:

Date _____

Clinic Attended _____

If this card is handed in at a clinic outside of _____, please forward to:

_____

(name and address of health institution)

1. Partners of patients with STDs are very likely to be infected and may be asymptomatic.
2. STDs may be managed syndromically *(see Chapter 8)* without etiologic confirmation.
3. The likelihood that a patient has an STD is very high in the following syndromes:

- Urethritis in males
- Genital ulcer disease in males and females
- Pelvic inflammatory disease
- Gonococcal ophthalmia neonatorum

Therefore, the partners (or the parents of babies) of these patients should receive epidemiologic treatment for the syndrome.

Vaginal discharge is less specific for the presence of an STD. The decision to treat male partners of women with vaginal discharge should be made based on the overall prevalence of STD in the community and the availability of laboratory diagnosis. For example, if speculum examinations are performed, the presence of cervical mucopurulent discharge is a specific enough clinical sign to suggest infection with either gonococcal or chlamydial infection.

4. Partners of persons with reactive syphilis serology should be referred and either tested for syphilis or treated epidemiologically.

Focusing outreach efforts on particular types of partners will have different effects on the prevalence of STD in a population *(see Chapter 13)*. If partner notification can identify partners most likely to transmit infection to others (core groups), then the disease control impact will be greater *(see Table 3)*. If notification efforts identify monogamous female partners, however, the program will primarily prevent complications of STDs in these female partners and their infants. Some programs have used male index patient reports to identify high risk settings (i.e., brothels) rather than individuals. With this information, intensified treatment and prevention efforts can be directed more effectively. Thailand, for example, used reports of male STD clients to identify previously unknown sites used by commercial sex workers.

Table 3
Feasibility of Partner Notification and Relative Impact on STD Program by Type of Partner

Type of partner	Feasibility	Impact on Program
Spouse/steady partner	+++*	+
Casual partner	++	++
High risk partner	+	++++

**In some cultures it is unacceptable for women to refer male partners.*

What to Refer

The following STD syndromes should be included in a partner referral program.

Partners of male index patients with:

- Urethritis
- Genital ulcer disease
- Positive syphilis serology
- Partners of mother of baby with gonococcal ophthalmia neonatorum

Partners of female index patients with:

- Genital ulcer disease
- Pelvic inflammatory disease
- Positive syphilis serology
- Purulent cervical discharge
- Infant with gonococcal ophthalmia neonatorum

The decision to treat male partners of women with vaginal discharge should be made based on the overall STD prevalence in the community and the availability of other laboratory diagnostics.

Who to Refer

Although from a public health point of view treating high risk partners will have the greatest impact on the prevalence of STDs in a population, in reality, STD patients should be encouraged to refer all sexual partners. The importance of interventions targeted at high risk groups is discussed in Chapter 13.

Specific, culturally appropriate messages can enhance the motivation of the index patient to refer his/her partners. For example:

- The desire for a healthy baby in a pregnant woman with reactive serology
- The risk of infertility in a wife of a man with urethritis in cultures where many children are desired

How to Refer

At a minimum, all health-care providers seeing STD patients should encourage patients to refer their sexual partners for treatment. Although this is inexpensive and easy, it has several disadvantages.

- There will be no record of the disease exposure of the referred partner unless the partner can be linked back to the original patient. As such, since the partner may be asymptomatic, epidemiologic treatment is impossible.
- There are no records for evaluation of the referral system. Is the health-care provider informing patients to refer their partners? What percentage of patients actually refer in their partners?

By introducing a referral card to be given by the index patient to the partner(s) the above mentioned disadvantages can be overcome. The card should contain, at a minimum:

- Diagnosis of the index patient (often coded for confidentiality)
- Instructions for the partner on where to seek care *(see section, "Partner Notification in Clinic Settings")*

Partner cards for monitoring the proportion of partners seeking care could be designed in several ways. Sequential serial numbers could identify index patients on the cards; portions of the cards could be detachable and retained in the clinic to link to index patients. Alternatively, carbon copies could be retained in the clinic.

The decision to upgrade a referral system to include provider referral would be costly and must be carefully weighed against other STD program needs.

CONCLUSION

In conclusion, no single type of partner notification program can be designed to suit the needs of every country because each program must operate in a unique social, cultural and medical environment. However, some components of a program can be implemented almost universally at low cost. It has been shown in several sites that simple patient referral using cards given to the index patient can lead to partner treatment rates of up to 50 percent of the index patients seen.

However, at this point, the cost benefit of establishing a provider referral system is unknown. For most programs in developing countries, it is not a realistic option.

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CHAPTER 10

The STD Laboratory

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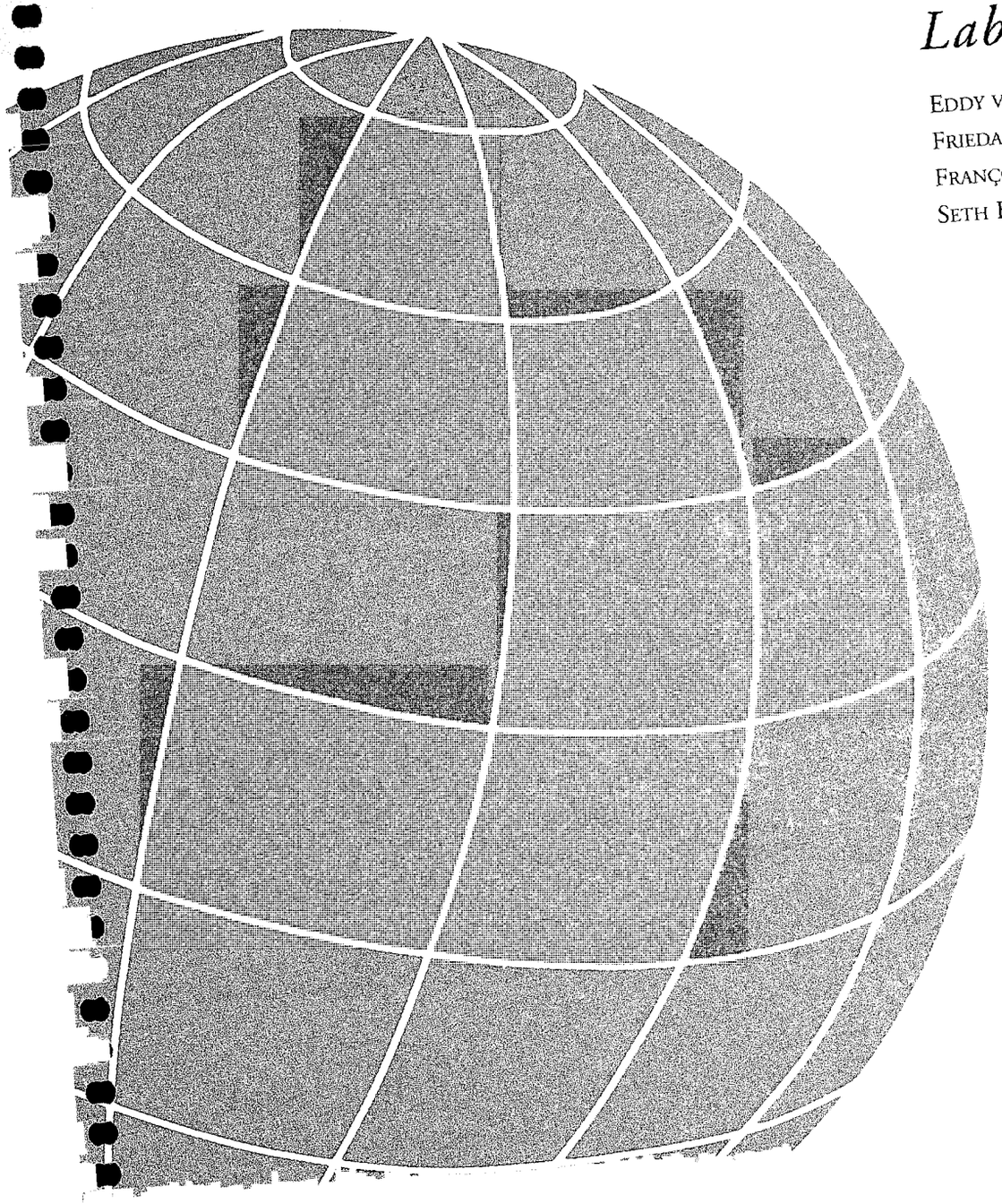

preview CHAPTER 12

The STD Laboratory

THE STD LABORATORY

This chapter helps STD program managers determine the appropriate level of laboratory support for their programs by providing criteria for selecting lab tests and describing how testing can complement the syndromic approach to STD case management.

ROLE OF THE LABORATORY

The primary role of the laboratory is to support decision making:

- In clinical practice
- For public health

CLINICAL PRACTICE

A laboratory can become involved in the following three types of STD activities:

- Diagnosis
- Case finding
- Screening

PUBLIC HEALTH

For public health purposes, laboratory tests are used to do the following:

- Help document the epidemiology of STDs
- Provide operational research
- Provide quality control

CRITERIA FOR LABORATORY TEST SELECTION

- Validity
- Reliability
- Feasibility
- Acceptability

LABORATORY ORGANIZATION

Laboratory procedures usually available at the three successive levels of clinical infrastructure are the following:

- **Peripheral:** microscopic examination of fresh and stained specimens, possibly KOH sniff test and nontreponemal syphilis screening test.

- **Intermediate:** microscopy, culture of *Neisseria gonorrhoeae,* antigen detection of *Chlamydia trachomatis,* and a number of serological tests, including HIV testing.
- **Central:** may be the same as at the intermediate level or more extensive, depending on the level of decentralization.

ANTIMICROBIAL SUSCEPTIBILITY SURVEILLANCE OF *N. GONORRHOEAE*

The recommended antibiotics for treating gonococcal infections are not available or affordable in many developing countries, so it is particularly important to monitor the susceptibility of less expensive antibiotics in these countries. Surveillance data can be used to develop and update appropriate treatment guidelines for managing gonococcal infections at the primary health-care level.

LABORATORY COSTS

Detailed cost-effectiveness studies of health care based on laboratory testing and diagnosis require assessment of indirect as well as direct costs (see section on cost of laboratory testing).

SYNDROMIC MANAGEMENT APPROACH

Use of the syndromic management approach *(see Chapter 8)* eliminates the need for diagnostic tests or simplifies the testing required. This approach is of adequate sensitivity and specificity for urethritis in males and genital ulcers in both sexes, but tends to have lower sensitivity and specificity when used for management of female genital discharge.

DIAGNOSTIC LABORATORY APPROACH

A laboratory approach is described for four major syndromes: (1) urethral discharge, (2) vaginal discharge, (3) lower abdominal pain, and (4) genital ulcer disease (GUD).

LABORATORY PROCEDURES

Laboratory procedures are described for the major STDs: gonorrhea, *Chlamydia trachomatis* infection, syphilis, genital herpes, chancroid, donovanosis, candidiasis, trichomoniasis and bacterial vaginosis. Table 1 shows the recommended diagnostic tests for each disease at each level of laboratory capability.

CONCLUSION

Many infections are asymptomatic, especially in women; even when symptomatic, they may have different causes. Simple, inexpensive diagnostic laboratory tests are urgently needed, particularly to detect *N. gonorrhoeae* and *C. trachomatis* in women.

INTRODUCTION

The syndrome approach to STD case management *(see Chapter 8)* is designed to improve STD diagnosis and treatment at health care facilities where laboratory tests are not available, but it can also be adapted for use when testing is available. Laboratory support is needed to detect infections in asymptomatic individuals, to identify serious infections that do not have specific signs and symptoms, to monitor resistance to antibiotics and to validate treatment algorithms.

This chapter is designed to help managers determine the appropriate level of laboratory support for their STD programs. It describes the role of the laboratory in STD control, criteria for selecting laboratory tests, and the organization of STD laboratories. It also explains when laboratory tests are needed and summarizes the laboratory procedures for detecting the major STDs.

ROLE OF THE LABORATORY IN STD CONTROL

The laboratory is meant to support decision making in STD control at both clinical and public health levels. Strengthening of laboratory infrastructure should always be subordinate to requirements for STD control interventions.

The primary role of the laboratory is to support decision making

- In clinical practice
- For public health

CLINICAL PRACTICE

Laboratory tests improve the diagnostic **specificity** of symptomatic STDs, as well as the diagnostic **sensitivity** of asymptomatic STDs. A laboratory can become involved in three types of STD control activities:

- **Diagnosis:** to assist in management of patients with symptoms of STD
- **Case finding:** detection of STD in patients seeking health care for other reasons
- **Screening:** voluntary assessment of STD among populations or selected individuals not seeking health care

Diagnosis of symptomatic patients

Given that symptoms and signs of lower genital tract infections are not specific, particularly in women, laboratory tests are helpful to differentiate serious infections, i.e., cervicitis, from milder but more common infections, i.e., vaginitis. Simple laboratory tests incorporated in syndromic management of urethral discharge also help distinguish between mixed and single infections, reducing the administration of unnecessary antibiotics.

Case finding in asymptomatic individuals

Laboratory tests increase the sensitivity of STD diagnosis, allowing detection of infections in asymptomatic individuals. Case finding of asymptomatic STDs is most important in female patients, who carry the burden of STD complications and sequelae. Case finding is even more important in pregnant women because laboratory testing helps prevent the adverse consequences of syphilis, gonococcal and chlamydial infection in newborns *(see Chapter 9).*

PUBLIC HEALTH

Laboratory tests play a key role in public health decision making. They help document the epidemiology of STDs in target populations, regardless of the symptoms. Results are used to advocate STD control interventions and assess their impact. Lab tests are essential for operational research, such as validation of guidelines for syndromic management of symptomatic STDs or definition of appropriate STD treatment guidelines. Reference laboratories are also used to monitor the quality of results produced by clinical laboratories and to train their staff.

CRITERIA FOR LAB TEST SELECTION

The criteria for determining which lab test to use are similar to those for choosing any evaluation indicators.

Selection criteria of laboratory test include:

- Validity
- Reliability
- Feasibility *(for the laboratory)*
- Acceptability *(including affordability)* for the patient

Validity refers to test sensitivity (percent of true positives) and specificity (percent of true negatives) of a test compared to those of the gold standard. The gold standard is the best available diagnostic test for a disease. In some cases, no single diagnostic test is available, and a combination of tests is needed, such as the "expanded gold standard" (positive culture or confirmed DNA amplification technique) presently in use for the diagnosis of *Chlamydia trachomatis* infection.

Lab test sensitivity partly depends on the prevalence of the disease. As the prevalence increases, so does the probability of encountering the disease in its acute stage with higher concentrations of detectable particles. Usually, cost increases with validity.

Reliability is the ability to produce similar results for the same biological sample. Reliability increases with the validity of the technique, but also depends on the ease of use. Techniques involving automated measurement of substances, such as enzyme immunoassays (EIAs), are intrinsically more reliable than those involving the technician's interpretation, such as microscopy. Direct fluorescent antibody testing (DFA) for *Chlamydia* can be extremely sensitive and reliable in expert hands, but even a simple test such as Gram stain examination of urethral discharge can have a low validity and reliability when it is used by a sloppy technician. Increasingly reliable techniques ("idiot-proof") are constantly being developed by lab test manufacturers, but they can be expensive. In addition, even the most reliable technique yields poor results when it is improperly standardized or not monitored through quality control procedures.

Beyond ease of use, the technical **feasibility** of a test for a laboratory depends on the operational requirements for the test, such as space, clean water, stable power supply and refrigerated storage of reagents. As health facilities become more distant from urban centers, these requirements become more difficult to meet. Sophisticated techniques also tend to require more spare parts and specific reagents. Even in major public sector laboratories, provision of spare parts and reagents is frequently overlooked. A survey conducted in a Latin American country reached the conclusion that 70 percent of all lab equipment in the public sector nationwide was out of order because of missing spare parts or reagents.

Acceptability of a test for patients usually depends on the type of biological sample requested. Saliva and urine production is painless and easier than having blood drawn. In some cultures blood samples can be extremely difficult to obtain. Not surprisingly, urethral swabbing in men, especially with a cytobrush, is probably the least acceptable. Painful or invasive techniques may be more acceptable to symptomatic patients, but painless and easy sampling is critical for case finding or screening of asymptomatic individuals. Acceptability also increases when results are obtained quickly, which in turn depends on the organization of laboratory activities.

Finally, acceptability includes affordability when patients must pay for lab services. As a general rule, lab expenditures should not exceed the treatment costs saved by testing. Acceptance of lab expenditures is the lowest for case finding or screening of asymptomatic subjects, including asymptomatic contacts of STD patients.

LABORATORY ORGANIZATION

Clinical Practice

Clinical infrastructure in the public sector is organized at three successive levels. Patients are first seen in peripheral (primary health care or first-encounter level) health units. Patients who need to be referred are sent to intermediate (regional) health facilities and from there to central (national) facilities. Clinical laboratories are generally organized at the same three levels *(see Table 1)*.

Peripheral laboratories are attached to health centers and first referral (health district) hospitals. Lab procedures at this level usually include microscopic examination of fresh and stained specimens. In syndromic

Table 1

Recommended Diagnostic Tests by Level of Laboratory Capability

Gonorrhea	Smear (Gram, methylene blue, safranin)	+	+	+
	Culture	-	+	+
	ß-lactamase	-	(+)	+
	Antimicrobial susceptibility	-	-	+
Chlamydia trachomatis infection	Antigen detection			
	DFA	-	(+)	+
	ELISA	-	-	+
	DNA hybridization	-	-	(+)
	Culture	-	-	+
	Serology	-	-	+
Syphilis	Darkfield microscopy	-	(+)	+
	RPR	(+)	+	+
	TPHA	-	(+)	+
	FTA	-	-	+
	IgM	-	-	+
Genital herpes	Antigen detection	-	-	+
	Culture	-	-	+
	Serology	-	-	+
Chancroid	Culture	-	-	+
	Antimicrobial susceptibility	-	-	+
Donovanosis	Smear (Leishman, Wright)	-	(+)	+
	Histopathology	-	-	+
Trichomoniasis	Wet mount microscopy	+	+	+
	Culture	-	-	+
Candidiasis	Wet mount (cv. + 10% KOH)	+	+	+
	Culture	-	-	+
Bacterial vaginosis	Wet mount, stained smear pH, KOH snifftest	+	+	+

+ yes
(+) yes, if possible
- no

management of urethral discharge, microscopy helps single out nongonococcal infection. For vaginal discharge, microscopy helps differentiate trichomoniasis from candidiasis and bacterial vaginosis. Simple additional tests to identify bacterial vaginosis are the KOH sniff test and measurement of pH of vaginal fluid. Lab procedures may also include simple nontreponemal syphilis screening tests: rapid plasma reagin (RPR) or Venereal Disease Research Laboratory (VDRL).

It is strongly recommended that lab procedures included in STD diagnosis and case-finding guidelines at first-encounter level be available on site in order to optimize acceptability and coverage. RPR testing in pregnant women is a good illustration of a service that should be available at peripheral health centers. Systematic referral elsewhere of asymptomatic subjects for such a simple test is both expensive and time-consuming and significantly affects coverage.

Intermediate-level laboratories are commonly situated in regional or provincial hospitals. Their diagnostic requirements are greater, and better infrastructure and skilled manpower are available. Lab tests might include culture of *Neisseria gonorrhoeae* and identification of penicillinase-producing strains. They might also include antigen detection of *Chlamydia trachomatis,* depending on staff workload and available resources. Serology might include HIV testing (enzyme-linked immunosorbent assay [ELISA] or particle agglutination) as well as confirmatory tests for syphilis (fluorescent treponemal antibody [FTA] or microhemagglutination assay for antibodies to *T. pallidum* [MHA-TP]).

Central laboratories are usually located in the capital city or in a university hospital. The range of diagnostic tests performed varies according to the available human, material and financial resources and the workload. There is no sharp distinction between what should and could be performed at the intermediate versus the central level. These decisions depend on the organization of health services in a country. One central reference laboratory may be quite satisfactory in a small country. In big countries centralization of reference cases in the capital city is unrealistic; therefore, some decentralization of lab testing at the regional level is necessary.

Constraints to providing laboratory services in developing countries include:

- Shortages of supplies and reagents
- Failure of power and water supplies
- Inadequate maintenance of equipment
- Weak technical ability of personnel
- Lack of supervision and quality control
- Absence of continuing education
- Lack of primary and continuing education for health care providers on the usefulness of laboratory diagnostics

All these factors contribute to low motivation among laboratory technicians and may result in poorly maintained and dirty workplaces, delays in specimen processing, use of out-of-date reagents, mislabeling of specimens, poorly maintained registers, and frequent personnel absences.

A few examples from the field illustrate the kind of problems resulting from these constraints:

- In a clinic with an average of at least 100 STD patients each day, women had to wait several hours for treatment until clinicians received the results of Gram stains performed on three cervical smears per women. When asked, the clinicians reported that they treated for gonococcal infection based upon their clinical impressions, even when the lab results returned negative, demonstrating a lack of confidence in the laboratory support services.
- In another clinic, pregnant women were routinely sent to a laboratory where technicians asked them to self-collect a vaginal specimen for wet mount and Gram stain using a swab. Vaginal swabs often arrived at the laboratory dried out, and Gram stain results mentioning the presence of any Gram-negative diplococci were interpreted by the clinicians as confirmatory of gonococcal infection.
- At a metropolitan clinic with a high volume of patients, lab tests such as wet mounts, Gram stains and gonococcal cultures were performed with

nonstandardized disc diffusion sensitivity testing on all men presenting with urethritis and all women presenting with vaginal discharge. As a result of such high-volume testing, the laboratory could not assure the necessary quality. A critical review of the indications for laboratory tests and laboratory techniques improved the quality of work and morale of the laboratory workers and the clinicians who depended on their results.

Introduction of STD diagnostic tests is difficult and expensive. In planning STD laboratory development and diagnostic activities, it is essential to consider the following factors:

- The prevalence of STDs should be of sufficient magnitude to justify the effort.
- Sufficient logistical support and financial and human resources should be available to maintain the laboratory.
- The technology and methodologies used should be appropriate for the technical capacity and educational levels of laboratory staff.
- Clinicians should choose treatment or preventive measures based on laboratory test results.
- Additional tests should not be introduced at the expense of higher priority needs; the most cost-effective STD case management approach should be employed.
- Follow-up, evaluation, coordination and quality control should be assured.

Public Health

Among the major public health needs for STD control are prevalence studies for guideline validation *(see Chapter 8)* or STD surveillance and antimicrobial susceptibility surveillance of *N. gonorrhoeae (see Chapter 15)*. The most important requirement for public health data is **reliability,** which depends on skilled manpower and quality control procedures. It is critical that centralized labs are reliable because samples taken for public health purposes should be forwarded from different sites in the country to one reference laboratory, usually located in the capital city. When this is not technically feasible, however, some decentralization should be considered.

The cost of public health testing should be supported by the public sector, since patients cannot be expected to pay for tests they have not requested. Also because people do not request these tests, the least invasive methods of specimen taking should be used to increase acceptability.

Total separation of public health and clinical testing is not a cost-effective use of equipment and trained personnel. In fact, some laboratories combine both activities because fees for clinical tests help raise money for public health testing. However, the two should not be combined at the expense of public health priorities.

Antimicrobial Susceptibility Surveillance of *N. gonorrhoeae*

Rationale

Surveillance of the antibiotic susceptibility of *N. gonorrhoeae* is a major public health issue. In many countries of the developing world, antibiotics currently recommended by WHO or CDC for gonococcal infections are neither available to nor affordable for STD patients. Given their variable resistance profile, it may be possible to recommend less expensive antibiotics such as cotrimoxazole or kanamycin, provided their efficacy is regularly monitored. Thus, susceptibility surveillance data are used primarily to help develop and update appropriate treatment guidelines for managing gonococcal infections at the primary health care level. **Susceptibility testing on an individual basis is not justified.**

Antibiotics to be Tested

Penicillin and tetracycline are tested for epidemiological rather than practical purposes, since gonococcal resistance to both drugs is usually high in many countries. Less expensive drugs that should be tested include trimethoprim-sulfamethoxazole and the aminoglycosides. Resistance to fluoroquinolones is rapidly increasing when they are widely used, making

monitoring essential. Spectinomycin and second-and third-generation cephalosporins are still highly effective, but monitoring could document the emergence of resistant strains.

Laboratory Methodology

Antimicrobial resistance in *N. gonorrhoeae* is both chromosome- and plasmid-mediated. Penicillinase-producing *N. gonorrhoeae* (PPNG), also termed beta-lactamase-positive *N. gonorrhoeae,* refers to plasmid-mediated resistance to penicillin, which is detectable with simple and inexpensive tests. Tetracycline-resistant *N. gonorrhoeae* (TRNG) refers to plasmid-mediated resistance to tetracycline. No simple test can detect TRNG. The corresponding plasmid must be identified with biomolecular techniques. Alternatively, resistance to tetracycline is assumed to be plasmid-mediated when reaching levels far beyond those observed with chromosomal resistance.

The **agar-plate dilution technique** is the reference method for quantitative testing of chromosome-mediated resistance to antibiotics. Bacterial growth is examined on culture media with various concentrations of antibiotics incorporated. Results are expressed in MICs (minimal inhibitory concentrations). Unfortunately, the technical requirements for this method make it inaccessible in developing countries, except in a few experienced reference laboratories.

The **disc-diffusion technique** involves examining bacterial growth on culture plates around calibrated paper discs impregnated with antibiotics. It is both economical and simple to use. Unfortunately, with *N. gonorrhoeae* this method has been standardized only for a limited number of antibiotics.

The most recent E test, produced by AB Biodisk of Sweden, combines the advantages of the agar-dilution technique with the simplicity of disc testing. Plastic strips with continuous antibiotic gradients, allowing MIC determination, are applied onto the surface of culture plates. The E test is a reliable alternative to agar-dilution for *N. gonorrhoeae.* However, it is expensive and has not yet been fully recognized as a reference method.

Frequency

Some Western countries, such as the United States and Canada, conduct ongoing gonococcal susceptibility surveillance in sentinel STD clinics throughout the country. In developing countries, however, surveillance data are used primarily to validate treatment guidelines. Guideline validation is an intermittent process, so susceptibility surveillance may be conducted through specific surveys at regular intervals, particularly when laboratory resources are limited.

Sample Size

It is estimated that 100 to 150 gonococcal isolates need to be collected to measure a significant shift in antibiotic resistance between two surveys.

Sample Population

Consecutive male patients with visible urethral discharge attending primary health care facilities are the first choice for the sample population because gonococcal yields are the highest and it is easier to take specimens from men than from women. Enrolled patients should be representative of STD patients at first-encounter level within the formal health sector. Patients entering the survey should not have been referred from other health care services. Self-medication, widely practiced in many developing countries, should not lead to exclusion from the survey but should be noted in the data collection process.

In some countries, male patients are very hard to reach because the stigma associated with STDs leads to widespread self-medication. Female commercial sex workers may be a second best option for a sample population, but specimen taking is more difficult because they are women, gonococcal prevalence may be lower, and the representativeness of the overall population questionable.

Selection of Sample Sites

The number and geographic distribution of sites included in the survey should depend on how representative each site is of resistance patterns in the country as well as logistical constraints.

Table 2

COSTS OF RAPID PLASMA REAGINS (RPR) SCREENING IN AN ASYMPTOMATIC POPULATION OF 10,000 PEOPLE FOR THREE DIFFERENT PREVALENCE RATES OF DISEASE (RPR SENSITIVITY 85%, SPECIFICITY 98%)

Prevalence	1%*	5%	25%
Positive Predictive Value (PPV)	30%	69.1%	93.4%
N of true positives detected	85	425	2,125
Total N of reactives detected	283	615	2,275
Screening cost [a] (U.S. dollars)	$9,000	$9,000	$9,000
Cost for management of reactives detected [b]:			
laboratory (RPR titration)	$170	$369	$1,365
medical care	$849	$1,845	$6,825
Total cost	$10,019	$11,214	$17,190
Cost to detect one true positive	$107.90	$22.00	$4.90
Total cost per true positive	$117.90	$26.40	$8.10

(a) blood collection: $0.5; laboratory testing: $0.4
(b) aboratory testing: $0.6; medical care: $3.0
* *For a prevalence of syphilis of 1%, a test with a sensitivity of 85% and a specificity of 98% will detect in a population 10,000 people 85 cases of syphilis (true positives) and 198 reactive cases who do not have the disease (false positives); 15 true cases of syphilis will not be detected (false negatives) and 9,702 people will correctly be identified as not having the disease (true negatives).*

		Syphilis +	Syphilis −		
RPR	+	85	198	283	sensitivity: 85/100 = 85%
	−	15	9,702	9,717	specificity: 9702/9900 =98%
		100	9,900	10,000	positive predictive value: 85/283 = 30%
					negative predictive value: 9702/9717 = 99.8%

COST OF LABORATORY TESTING

Careful attention should be given to the cost-effectiveness of laboratory testing. Such testing is expensive and adds to the complexity of providing care. In many low-income countries, per capita health care expenditures are less than $10 per person; therefore, widespread testing for most STDs using currently available tests is unlikely. Detailed cost-effectiveness studies of health care based on laboratory testing and diagnosis are very complex and require assessment of indirect costs. Direct costs, which include equipment, supplies, reagents, drugs and labor, can be calculated more easily. An illustration of how to calculate the direct costs for screening and treatment of syphilis is given in Table 2.

SYNDROMIC STD MANAGEMENT APPROACH

The use of a cluster of signs and symptoms to determine therapy without making a definitive etiologic diagnosis is referred to as syndromic management *(see Chapter 8)*. Use of these methods either eliminates the need for diagnostic tests or simplifies the testing required.

Although of adequate sensitivity for urethritis in males and genital ulcers in both sexes, the syndromic approach tends to have lower sensitivity and specificity when used for management of female genital discharge. Recently attempts have been made to supplement identification of signs and symptoms with risk assessment questions or with non-specific, simple diagnostics like detection of leukocyte esterase, an enzyme in white blood cells. On the other hand, management of certain STD conditions, such as pelvic inflammatory disease, requires a syndromic approach, regardless of available resources.

DIAGNOSTIC LABORATORY APPROACH

URETHRAL DISCHARGE

Cases of urethral discharge can be treated based on clinical examination according to syndromic management guidelines, but laboratory tests are required to distinguish between nongonococcal and gonococcal urethritis. The presence of leucocytes and typical intracellular diplococci (gonococcal urethritis) or the presence of leucocytes without intracellular diplococci (nongonococcal urethritis) can be detected through microscopic examination of a smear of urethral exudate stained with methylene blue, safranin or Gram's method. Concomitant gonococcal and nongonococcal infections will **not** be identified with this method. Since microscopy of stained smears has a sensitivity of greater than 95 percent for gonococcal urethritis, culture for the isolation of *N. gonorrhoeae* is not essential for diagnosis and clinical management.[1] However, isolation of gonococci, along with clinical monitoring of treatment response, may be important in monitoring antimicrobial susceptibility trends.

For screening or case finding of urethritis among asymptomatic men, the collection of urethral specimens is an invasive method, not much appreciated by the participants. A noninvasive alternative is the collection of first-catch urine for detection of leucocyte esterase. Leucocyte esterase has a reported sensitivity for detecting infectious urethritis ranging from 41 to 100 percent, but it does not allow differentiation between gonococcal and nongonococcal urethritis. The specificity of the leucocyte esterase method varies between 35 and 100 percent; consequently, the predictive value of a positive test may be very low.[2-7]

VAGINAL DISCHARGE/LOWER ABDOMINAL PAIN

Wet mount microscopy is very useful for the diagnosis of trichomoniasis, candidiasis and bacterial vaginosis (BV). A pH test, a KOH sniff test and a Gram stain of vaginal discharge may contribute to a reliable diagnosis of BV. Diagnosis of gonococcal and chlamydial cervicitis, infections with potentially serious sequelae, is even more important, but unfortunately, simple methods for diagnosing these infections are not available. Gram stain microscopy has a very low sensitivity for detecting gonorrhea among women; culture remains the method of choice.[8] Diagnostic assays for *Chlamydia trachomatis* infection include direct fluorescent antibody test, enzyme immunoassays, DNA hybridization, cell culture and DNA amplification techniques (polymerase chain reaction (PCR) and ligase chain reaction (LCR)).

GENITAL ULCER DISEASE

Genital ulcers may result from syphilis, chancroid, herpes, donovanosis, or (rarely) lymphogranuloma venereum (LGV). Management of patients can be

based on clinical examination and application of treatment algorithms. Essential procedures for definite diagnosis of the different genital ulcer diseases are:

- Darkfield microscopy for treponemes
- Wright or Leishman stain for *Calymatobacterium granulomatis*
- Culture for *Haemophilus ducreyi*
- Culture or direct immunoassay for herpes simplex virus
- Serology for syphilis and LGV

LABORATORY PROCEDURES

GONORRHEA

Gonorrhea produces a purulent exudate, but signs and symptoms of disease may either be absent or indistinguishable from those of chlamydial infection; therefore, laboratory tests are needed for diagnosis and case finding as well as for test-of-cure. Accurate methods for the diagnosis of gonorrhea are direct microscopy of a stained urethral discharge smear in men and cultures of all other types of specimens.

Direct microscopy (for males)

Simple staining of a urethral specimen with methylene blue or safranin may offer a quick and reliable diagnosis of gonorrhea in men, but the Gram stain, which gives more specific results for specimens containing mixed bacterial flora, remains the standard method.

Nonculture gonorrhea detection techniques

Different culture-independent tests for gonorrhea detecting oxidase, endotoxin, antigen or DNA have been compared with a standard culture technique. All these procedures are more expensive and less efficient than a culture technique for extragenital specimens and for specimens containing small numbers of organisms, (except for DNA amplification tests).[9-13]

Several antibody techniques have been used to detect gonococcal antibodies in serum. None of the currently available methods are useful for diagnostic purposes because they cannot differentiate recent from past infection.

Culture identification

The observation of oxidase-positive Gram-negative diplococci with a gonococcus-like colony morphology in a cultured specimen offers a sufficient and reliable identification of *N. gonorrhoeae* for routine diagnosis in genital specimens. For extragenital isolates as well as for research, further characterization is recommended.[9] Carbohydrate degradation tests (glucose, maltose, lactose and sucrose) are commonly used, sometimes in combination with enzymatic substrate tests.[14-17] An immunologic confirmation assay using monoclonal antibodies is a very reliable but more expensive alternative.[16,18]

In vitro *antimicrobial susceptibility testing*

Antimicrobial susceptibility testing of gonococcal isolates is not required for guidance of gonorrhea treatment in an individual patient because currently recommended treatment regimes by WHO are adequate to cure gonococcal infections resistant to penicillin, ampicillin and tetracycline. Susceptibility testing may be recommended in the following circumstances:

- In reference laboratories for epidemiological investigations to provide susceptibility information and monitor trends in drug resistance
- In STD laboratories that conduct a high volume of tests to help monitor the clinical efficacy of recommended treatment regimens
- In studying new antimicrobial agents
- In providing information to clinicians in cases of treatment failure

It is important to remember that treatment failure may be due to gonococcal resistance to currently recommended drugs, but more common reasons include poor compliance with therapy, reinfection or coinfection with *Chlamydia trachomatis*. If performed without rigorous standardization, *in vitro* antimicrobial susceptibility testing may generate unreliable results.

Detection of plasmid-mediated antimicrobial resistance in vitro

Penicillinase-producing *N. gonorrhoeae* (PPNG): many isolates of *N. gonorrhoeae* are resistent to penicillin and ampicillin because they produce an enzyme, ß-lactamase, that results in hydrolysis of these drugs. Common rapid ß-lactamase detection techniques include: the acidometric method, which uses a pH indicator to detect increased acidity from cleavage of the ß-lactam ring of penicillin; the idometric method, which detects a color change caused by the reduction of iodine by penicilloic acid; and the chromogenic cephalosporin method, which detects a color change of a chromogenic cephalosporin after hydrolysis of the ß-lactam ring.[19-21]

Tetracycline-resistant *N. gonorrhoeae* (TRNG): high-level tetracycline-resistant isolates of *N. gonorrhoeae* carrying a conjugative plasmid have become endemic in different geographic areas. TRNG can be determined by testing its ability to grow on a medium containing 10 mg of tetracycline per liter. The minimum inhibitory concentration (MIC) of tetracycline is $\geq$16 mg/liter.[22]

Chlamydia trachomatis *Infection*

Chlamydia trachomatis is an important cause of urethritis and cervicitis. Symptoms and signs of chlamydial infection may be extremely mild or totally absent, making early diagnosis and treatment less likely than with other STDs. Untreated chlamydial urethritis in men can evolve to epididymitis. In women, the cervix is most commonly infected and infection frequently spreads to the urethra; chlamydia can also invade the endometrium and fallopian tubes, resulting in endometritis or salpingitis. Coinfection with gonorrhea is common.

With the advent of new technologies, the current reference test for the diagnosis of *C. trachomatis* infection is either positive tissue culture or positive DNA amplification test confirmed by another test using a different technique, such as direct fluorescent antibody (DFA), or the same DNA amplification technique directed toward a different target, such as the MOMP (major outer memebrane protein) gene. The culture procedure, however, is expensive, slow, labor-intensive, technically difficult and beyond the capacity of most laboratories. In competent hands, the specificity of culture is 100 percent. Because technical difficulties can interfere with the reliability of the culture within a laboratory and unquestionably from one laboratory to the other, its sensitivity is estimated to be no more than 70 to 80 percent.[23] Cervical culture for *C. trachomatis* has a 65 percent sensitivity compared to the LCR assay of urine.[24]

Different nonculture techniques (immunofluorescence, enzyme immunoassay, DNA hybridization) developed during the 1980s, which are easier to perform and less expensive than culture, are now widely used. Many publications compare the evaluation of nonculture methods with that of cell culture, but an estimation of their actual sensitivity and specificity is extremely difficult since the reference culture technique does not meet the criteria of a real "gold standard."[25]

Direct microscopy (for males)

In a patient who has a history of acute onset of urethral discharge and has not received any antibiotic therapy, a Gram stain of a urethral specimen demonstrating polymorpholeukocytes without the presence of Gram-negative diplococci has a high predictive value for chlamydial infection.

Cell culture

Many cell lines are suitable for the growth of *Chlamydia,* but the method of choice in most laboratories is to add centrifuged specimens to cycloheximide-treated McCoy cell monolayers, incubate them at 36°C for two to three days, then stain them with fluorescein-labeled monoclonal antibody.[26,27] The addition of a blind passage enhances the sensitivity of the culture method, but may create a clinically unacceptable delay in diagnosis.[28,29]

Direct fluorescent antibody (DFA) test

Fluorescein-labeled monoclonal antibodies to the species-specific epitope of major outer membrane proteins can detect elementary bodies (EBs) of *C. trachomatis* in clinical specimens.[30] The procedure is rapid

and simple to process, but laborious and tedious to read and not recommended for processing large numbers of specimens. Microscopic reading of results is subjective, and the reliability of the test depends on the expertise of the observer.[31,32] Investigators do not always use the same cutoff number, or number of EBs necessary to consider a specimen positive, which influences the sensitivity of the method.[33-35] Overall, DFA shows acceptable accuracy for diagnosis in symptomatic patients and for case finding in high prevalence populations, but lacks the sensitivity to detect the small numbers of organisms often found in asymptomatic subjects, particularly in low prevalence populations.[36,37]

Enzyme immunoassay (EIA)

EIA methods are more suitable than DFA for batch processing of large numbers of specimens. This method is also more objective than DFA because the results are read with a photometer. The overall sensitivity and specificity of EIA and DFA are similar.[37] Most of the currently available EIAs include a confirmation (neutralization or blocking) assay performed on positive specimens. During retesting by EIA, the presence or absence of chlamydial antigen in a sample previously reactive in EIA can be confirmed by selective inhibition of the antigen by *Chlamydia*-specific immunoglobulin.[38,39]

New easy-to-use membrane immunoassays enable rapid diagnosis of chlamydial infection under field conditions.[40] These methods have a lower sensitivity and are therefore less accurate than the more classic immunoassays.

DNA probes, PCR and LCR

DNA hybridization methods have been recently applied to chlamydial diagnosis.[41] Commercially available tests are easy to perform and have been shown to be highly specific, but their sensitivity appears to be similar to that of DFA and most EIAs. Amplification of DNA sequences with PCR and LCR offer very high sensitivity. However, the high cost of PCR and LCR, the specialized laboratory equipment necessary, and the ease with which contamination with DNA can occur in the laboratory currently limit the use of this method in routine diagnosis.

Urine specimens

Obtaining urethral specimens by swab from men is an invasive method that causes some discomfort. The collection of first-catch urine samples is noninvasive and therefore more acceptable. Several studies have shown comparable sensitivities for nonculture methods (EIA or DFA) on urethral swabs and centrifuged sediments from urine samples.[42,43] Other studies have shown a significantly lower sensitivity of cell culture from urine samples than from urethral swab specimens.[44,45] The utility of urine samples from women for culture detection instead of cervical swabs has been debated.[23,46,47] Results obtained by DNA amplification techniques on urine specimens from both men and women and clinical samples (PCR and LCR) are very promising.[24]

Antibody detection tests

Various serological methods (complement fixation, microimmunofluorescence, enzyme immunoassay) have been used to study chlamydial infections in special situations, but their use for diagnostic purposes remains limited. Similar to serologic confirmation of other infections, serologic evidence of chlamydial infection can be obtained by demonstrating seroconversion or by a fourfold or greater rise in antibody titer in paired sera at least two weeks apart. The use of a single high titer for diagnosis of chlamydial urethritis and cervicitis is unreliable. It is diagnostically suggestive for lymphogranuloma venereum (LGV), reactive arthritis, epididmytis and pelvic inflammatory disease.[23,32]

Active LGV infections in general have complement-fixation (CF) titers of 1:64 or greater. However, high CF titers can be found in asymptomatic individuals and those with chlamydial infections with the non-LGV serovars. Micro-immunofluorescence (micro-IF) is more sensitive than CF because it is possible to determine the antigenic type of the infecting chlamydial strain. Micro-IF, however, is not routinely available and is used in a few specialized laboratories.

SYPHILIS

Venereal syphilis is acquired by sexual contact with an infected person with an open ulcer; the transmission of *T. pallidum* requires exposure of non-infected mucous membranes or skin abrasions to infectious lesions.

No structural or metabolic difference have been found that distinguish between spirochetes that cause venereal syphilis *(Treponema pallidum),* endemic syphilis *(T. endemicum),* yaws *(T. pertenue)* and pinta *(T. corateum).* Therefore, these organisms cannot be differentiated by laboratory tests, but only by clinical manifestations and through epidemiological studies, including inquiries to determine the mode of transmission.

Syphilis is a chronic infection with diverse clinical manifestations occurring in distinct stages, and each stage requires a different diagnostic approach. Treponemes can be identified in the primary and secondary stages. In the primary stage, treponemes are microscopically detectable in skin or mucosal lesions at the site of entry (primary chancre). During the secondary stage, they can also be detected in the papular rash lesion or in condylomata lata.

During the early primary stage serological tests are negative; antibodies usually appear one to four weeks after a lesion has formed. During the secondary stage, all serological tests are positive, and nearly all patients will show high antibody titers (>1:8) in nontreponemal tests. Serology remains positive during latency and the tertiary stage; however, approximately 20 percent of patients during late latency and 30 percent of patients with tertiary-stage syphilis may have nonreactive nontreponemal tests.

Congenital syphilis is acquired by transplacental transmission of *T. pallidum* from a pregnant woman to a fetus *(see Chapter 9).* Diagnosis of congenital syphilis is based on:

- Microscopic demonstration of *T. pallidum* in nasal discharge or skin lesions, when present
- Detection of specific IgM antibody in serum
- Demonstration of rising nontreponemal test antibody titers in serial serum samples during the first eight months of life

Direct microscopy

Darkfield microscopy is the only method that provides an instant diagnosis of syphilis in the primary and secondary stages. For reliable results, however, appropriate technical conditions usually found only in specialized laboratories are essential, including well-trained staff and adequate equipment and time.

The direct fluorescent antibody (DFA) test may be a more practical alternative to darkfield microscopy because the clinical specimens are fixed on a slide with methanol or acetone and laboratory examination can be done after transport. DFA also eliminates confusion with other spiral organisms and does not require motile organisms for syphilis diagnosis, so its specificity and sensitivity are higher than that of darkfield.[48] Failure to visualize the organism, however, does not exclude a diagnosis of syphilis. A negative result may mean that:

- An insufficient number of treponemes were present in the lesion.
- The patient was treated or partially treated recently.
- The lesion was approaching natural resolution.
- The lesion was not syphilitic.

Nontreponemal tests

All the current nontreponemal methods for syphilis are flocculation tests using cardiolipin, lecithin and cholesterol as antigen. The Venereal Disease Research Laboratory (VDRL) test was the first in the series of slide flocculation methods,[49] and the basic antigen composition in all newer tests is that of the VDRL. The antigen used in the VDRL test is not stabilized, so a working suspension must be prepared fresh daily. The VDRL should be performed on serum heated at 56°C before testing, and results must be read with a microscope at 100x magnification. This microscopic test, VDRL, is the only appropriate test for spinal fluid. Another microscopic method, the unheated serum reagin (USR) test, can be performed with a stabilized antigen on unheated serum.[50]

Table 3
Sensitivity and Specificity of Serological Tests for Syphilis

Test	Primary	Secondary	Latent*	Late*	(%)
VDRL	80 (74-87)	100	80 (71-100)	71 (37-94)	98
RPR-card	86 (81-100)	100	80 (53-100)	73 (36-96)	98
FTA-ABS	98 (93-100)	100	100	96	99
MHA-TP	82 (69-90)	100	100	94	99

** widely variable results reported in the literature*

In other flocculation tests, the reaction is visible to the naked eye. The most popular of these macro-vue methods is the rapid plasma reagin (RPR) test, which uses plastic-coated cards in place of slides and a stabilized antigen to which charcoal particles are added. The antigen is not coated on these particles. Instead, it is trapped in the lattice formed by the antigen-antibody complex in positive samples, making the reaction visible to the naked eye. The test may be performed on unheated serum or plasma.[51] Modifications of the RPR include the reagin screen test (RST), which uses a lipid-soluble black dye in place of charcoal;[52] the VDRL carbon antigen, which is similar to the RPR, and the toluidine red unheated serum test (TRUST), which uses toluidine red in place of charcoal to make the reaction visible.[53]

Treponemal tests

Specific treponemal tests detect antibodies against treponemal cellular components. The three different test procedures are: indirect immunofluorescence, haemagglutination and enzyme-linked immunosorbent assay. The fluorescent treponemal antibody-absorption (FTA-ABS) test is the most sensitive of all syphilis tests, but is technically the most difficult. Standard reading, high-quality and appropriate dilution of the conjugate, and the use of good antigen slides are essential for the reliability of the test.[54] Microhemagglutination assay for antibodies to *T. pallidum* (MHA-TP), *T. pallidum* hemagglutination assay (TPHA) or hemagglutination treponemal test for syphilis (HATTS) are easier to perform than FTA-ABS, have fewer variables, and are more practical for batch processing of large numbers of specimens.[55,56] Enzyme-linked immunosorbent assays (ELISAs) are designed for batch processing of specimens and are suitable for automation of serology.[57,58] The different treponemal tests have comparable sensitivity and specificity, except for primary-stage syphilis, where FTA-ABS is more sensitive than the other methods.

Appropriate use of serological tests

The sensitivity and specificity of nontreponemal and treponemal syphilis tests for the different phases of the disease are shown in Table 3. A reactive nontreponemal test may indicate a primary infection, a recent infection treated or not treated, or a false-positive result. False-positive results occur in general populations at a rate of 1 to 3 percent. The vast majority of false-positive sera show antibody titers of $\leq$ 1:4. However, low titers do not exclude syphilis and are often found in early primary, late latent and tertiary syphilis. Determination of nontreponemal serum titers through a quantitative procedure may be helpful for more accurate interpretation of results and for

evaluation of patients after treatment. To exclude false-positive results, it is necessary to perform a specific treponemal test.

A reactive treponemal test may indicate a primary or early infection, recent infection treated or not treated, or past infection. Once infected with pathogenic treponemes, the majority of subjects remain treponemal antibody-positive in tests for years—even for a lifetime—whereas the nontrepenomal tests usually revert to negative over time after successful treatment.

For borderline reactions, discordant nontreponemal-positive treponemal-negative reactions, and discordance with clinical impression, the tests should be repeated on a new serum sample. If disagreement persists, a different treponemal test may be done for final judgement. In incubating syphilis all antibody tests are negative. In early primary syphilis, combinations results may be obtained (nontreponemal-positive microhaemagglutination-negative, nontreponemal-negative microhaemagglutination-positive, or nontreponemal-negative microhaemagglutination-negative). To diagnose or exclude syphilis, the tests must be repeated after two to three weeks on a new serum sample. In such cases, it may be helpful to perform an FTA-ABS, since it is the most sensitive test for primary syphilis. Finally, when adequate treatment is started early in primary syphilis, patients may remain antibody-negative.

Seroreversion of nontreponemal tests to negative in patients adequately treated usually occurs within a period of six months to a few years and is associated with the duration of infection, previous infection, and the antibody serum titer at the moment of treatment. Seroreversion of treponemal tests also occurs within a few years in a minority of patients; this phenomenon is not yet clearly understood.

For diagnosis as well as for case finding of syphilis, serum samples should first be screened with a nontreponemal test. To date, the most popular nontreponemal test is the RPR 18-mm circle card test with mechanical rotation. In poorly equipped laboratories with low numbers of specimens to test, hand rotation of the cards is appropriate. The sensitivity of a "hand rotation" RPR is only slightly lower than that of a RPR with mechanical rotation. Thus, some samples with low antibody titer of $\leq$ 1:2 may appear negative with the hand rotation procedure. Specific treponemal antibody tests are used to confirm positive nontreponemal samples as well as for epidemiological studies. The most appropriate of these tests for routine work is the TPHA.

With nontreponemal tests, undiluted serum samples with high antibody titer occasionally appear nonreactive because of excess antibody. This phenomenon, known as a prozone effect, is sometimes observed in patients with secondary syphilis. Consequently, nonreactive undiluted samples from symptomatic patients should be diluted 1:16 to 1:256 and retested with a quantitative procedure.

Demonstration of treponemal IgM in serum

The synthesis of specific IgM antibodies is the first humoral immune response after infection in syphilis as well as in other bacterial or viral infections. In syphilis, treponemal IgM antibody is present not only in patients with early primary syphilis, but may also be found during the latent period and in patients with late disease. IgM decreases more slowly after spontaneous resolution of infection than after successful therapy.

Detection of IgM antibody is also very useful for the diagnosis of congenital syphilis. The presence of IgM antibody in the blood of newborns indicates prenatal syphilis infection of the child. In most children, however, IgM antibody only appears a few weeks to a few months after birth. The appearance of IgM in the cerebrospinal fluid (CSF) of patients with an intact serum/CSF barrier (i.e., normal serum/CSF albumin ratio) indicates active neurosyphilis because the molecular size of IgM prevents it from passing the placental barrier as well as the intact serum/CSF barrier.

The sensitivity of treponemal IgM detection is not optimal, but its observation may contribute to a more reliable interpretation of congenital syphilis, early

primary syphilis, late syphilis and reinfection of patients with a previous history of syphilis or other treponematoses. Disappearance of IgM can be a helpful test-of-cure for patient with early infection before seroconversion of nontreponemal tests is observed.

Genital Herpes

Herpes simplex virus (HSV) belongs to the group of alpha herpes viruses that become latent and cause persistent infections. Genital herpes is caused by HSV-2 in approximately 85 percent of cases; the remainder are caused by HSV-1. Primary HSV infection may be asymptomatic or characterized by the appearance of extensive vesicular or ulcerative genital lesions associated with inguinal lymphadenopathy, dysuria and fever. Recurrent genital herpes episodes are usually milder (except in an immunocompromised host) and are nearly always caused by HSV-2. Genital herpes is mainly diagnosed on clinical grounds; laboratory diagnosis is usually not essential.

Neonatal herpes is the most serious consequence of genital herpes infection. The virus is transmitted from the infected mother to the child during vaginal delivery. There is a need for rapid and reliable laboratory tests to detect HSV in asymptomatically infected pregnant women shortly before delivery, as well as to monitor neonates exposed to HSV at delivery.

Virus culture

Isolation of HSV in tissue culture remains the diagnostic laboratory method of choice. Culture performed on fresh vesicular lesions has a sensitivity of more than 90 percent. Culture from pustular lesions is positive in 70 to 80 percent of cases, whereas only 25 percent of crusted lesions give a positive culture result. Cultures from primary infection lesions recover a significantly higher amount of virus than culture from recurrent lesions.[59-61]

Cytopathic effect (CPE) typical of HSV can be recognized by a rounding of scattered cells, visible after one to seven days of incubation, depending on the concentration of virus in the clinical specimen. Other viruses may exhibit CPE similar to HSV; definite identification of HSV is recommended when an unusual type of CPE occurs or when specimens come from asymptomatic people. Identification and typing of HSV may also be useful for epidemiological and research purposes. Virus isolates can be confirmed as HSV and typed as HSV-1 or HSV-2 by neutralization tests, immunologic assays or nucleic acid hybridization.

Direct detection methods

Nonculture procedures are more practical for routine diagnosis of HSV infections because tissue culture facilities are not widely available. Detection of HSV antigen by immunologic techniques is currently the most common rapid diagnostic method. Immunologic procedures include immunofluorescence, immunoperoxidase, and enzyme-linked immunosorbent assay. The sensitivity of these antigen detection methods seems to vary between 70 and 95 percent.[62,63]

The most recent approach to rapid HSV diagnosis is DNA hybridization.[64] The amplification of DNA sequences by polymerase chain reaction may eventually offer a highly sensitive method useful for detecting HSV in asymptomatic pregnant women at term.[65]

Papanicolaou and Tzanck staining are no longer considered appropriate techniques for the diagnosis of genital herpes.[59] Although they are simple, inexpensive methods and can be used to demonstrate cytologic changes, such as giant cells or cells with intranuclear inclusions in smears from lesions and cervical specimens, they are not specific for HSV and have a low sensitivity compared to cell culture.

Serology

Serological assays for HSV antibody detection can contribute to diagnosing a primary infection episode if seroconversion or a fourfold or greater rise in antibody titer is observed between an acute phase serum sample

and a convalescent serum obtained 10 to 14 days later. In patients with recurrent infection, a significant antibody rise occurs in less than 10 percent of cases.

HSV antibody procedures include complement fixation, indirect immunofluorescence, neutralization technique, latex agglutination, hemagglutination and enzyme immunoassay. All these methods are sensitive for detection of IgG antibodies but cannot discriminate between recent and past HSV infection on a single serum sample. None of the commercially available tests can effectively differentiate between HSV-1 and HSV-2 infection because of extensive cross-reactivity. The major targets of serum antibodies are viral surface glycoproteins, and most of the immunogenic epitopes are common to both HSV-1 and HSV-2 types.

Recently several new proteins specific for HSV-1 and HSV-2 have been defined, including the glycoprotein gG of HSV-1, which differs significantly from the gG of HSV-2, and solid phase ELISA procedures using purified gG2 glycoprotein to specifically detect antibody to HSV-2 have become available. These tests can be used to determine specific IgG antibodies in patients exposed to HSV-2, including individuals who were previously infected with HSV-1 or other herpes viridae.[66]

CHANCROID

Chancroid is caused by *Haemophilus ducreyi* and is transmitted sexually by direct invasion of the organism through healthy or abraded skin and mucosa. The disease starts with a painful papule at the site of infection, resulting in a single or multiple ulcers. Inguinal lymphadenopathy may be present in up to 50 percent of patients. Extensive and persistent genital ulcers without inguinal bubo development may be observed in patients with immunosuppression caused by HIV infection. Due to the atypical presentation and superinfection of the ulcers, the accuracy of a clinical diagnosis varies between 40 and 80 percent.

Isolation and identification of H. ducreyi

To date, an accurate diagnosis of chancroid depends on the ability to culture *H. ducreyi*. Different media formulations have been used to isolate the organism with varying success. It has been shown that parallel use of both gonococcal (GC) and Mueller Hinton (MH) media may increase the isolation rate of *H. ducreyi* from ulcers to above 80 percent.

A presumptive identification of *H. ducreyi* may be based on colony characteristics, Gram stain, production of ß-lactamase and oxidase reaction. Colonies are nonmucoid, raised, granular, grayish-yellow in color, and can be pushed intact across the surface of the agar with an inoculating loop. They can be either translucent or opaque, and this variability in opacity gives the impression of a mixed, nonpure culture. *H. ducreyi* is a fastidious organism with limited biochemical activity. Hemin is required to initiate growth. Nitrate reduction and alkaline phosphatase are also important characteristics. *H. ducreyi* is oxidase-positive when tested with tetramethyl-p-phenylene-diamine, and almost 100 percent of isolates are ß-lactamase positive.

Direct detection methods

Direct examination of ulcer material on Gram-stained smears may contribute to the diagnosis of chancroid if typical small, Gram-negative bacilli grouped in chains or as "schools of fish" are observed. These typical features, however, are infrequently seen on smears from patients with culture-proven chancroid, resulting in a sensitivity of much less than 50 percent for the direct Gram stain.[67-69] In addition, because most genital ulcers harbor polymicrobial flora due to secondary contamination, the presence of Gram-negative bacilli may be misleading and frequently results in a false-positive diagnosis.[69,70] As a result of its low sensitivity and low specificity, a Gram-stained smear is not recommended for the diagnosis of chancroid.

Non-culture antigen and nucleic acid methods for *H. ducreyi* have been developed, but are still experimental. Fluorescein-labeled monoclonal antibodies have been used to detect *H. ducreyi* in clinical specimens. Antibody against a 62 kDa protein and against a 29kDa protein can be detected, respectively, from 50 percent and 74 percent of people with clinically sus-

pected chancroid.[71,72] These results are promising, but further evaluation and extensive screening of clinical specimens is required to determine the reliability of the procedures. DNA probes have been shown to be 100 percent sensitive and 100 percent specific for the identification of bacterial isolates, but their usefulness for direct diagnosis of chancroid remains to be established.[73,74]

Serology

The usefulness of serological tests for the diagnosis of active *H. ducreyi* infection is very limited, but serology has proven to be valuable for research and epidemiologic purposes.

The development of reliable serological tests depends on detailed information about the host immune response as well as antigen presentation by the infectious organism. Data on these mechanisms for chancroid and *H. ducreyi* are very limited. Clinical experience and experimental inoculation studies in humans suggest that there is probably no acquired immunity to *H. ducreyi.* More research is needed, however, to determine its antigenic composition, including specific immunogenic epitopes, and the kinetics of the humoral immune response to *H. ducreyi* in treated and nontreated patients with primary or repeated episodes of chancroid.

Circulating serum IgG and IgM antibodies to *H. ducreyi* have been detected with dot immunobinding and enzyme-linked immunosorbent assays.[75] With both methods, a qualitative and quantitative variation in antibody response is observed in patients with recent or past history of chancroid, but the factors influencing these response variations are not yet clearly understood.

Antimicrobial susceptibility testing

During the past two decades chromosomal resistance and high-level plasmid-mediated resistance have significantly increased among *H. ducreyi* isolates. Resistance patterns of clinical isolates, however, can vary greatly in geographically diverse areas. It has been observed that chancroid treatment failures are much more common in HIV-positive patients, but it is not yet clear whether treatment failure is significantly associated with HIV status or with increased antimicrobial resistance of *H. ducreyi* isolates.

To date, no standardized procedures exist for susceptibility testing of *H. ducreyi;* the only practical and reliable method is the agar dilution technique for determining minimum inhibitory concentrations. Commonly used media are MH agar or GC agar enriched with 1 percent hemoglobin, 5 percent fetal calf serum and 1 percent IsoVitaleX. Antimicrobial susceptibility testing of *H. ducreyi* is a cumbersome, technically delicate procedure and can only be successfully performed in specialized reference laboratories.

DONOVANOSIS

Donovanosis (Granuloma inguinale) is a chronic infection involving the skin, mucous membranes and lymphatics of the genitalia and perineal area. The disease starts with a subcutaneous nodule at the site of infection. This nodule erodes through the skin to form a beefy, red, granulomatous ulcer. Inguinal lymph nodes may become involved; the disease may spread hematogenously and may even result in cutaneous lesions at extragenital body sites.

Donovanosis is caused by *Calymatobacterium granulomatis,* which cannot yet be cultured on artificial media. Laboratory diagnosis depends on the visualization of Donovan bodies in smears from clinical lesions.

Direct microscopy

The sensitivity of microscopy of tissue samples crushed between two slides is below 40 percent for patients with clinically suspected lesions of donovanosis. Histological aspects observed in sections of a biopsy may be helpful to differentiate between donovanosis and other conditions. An ulcer with a mixed inflammatory infiltrate of plasma cells, neutrophils and histyocytes and with a conspicuous absence of lymphocytes, suggests granuloma inguinale. Demonstration of characteristic intracellular organisms (Donovan bodies) by Warthin Starry silver impregnation is diagnostic.[76]

Serology

Antibodies to *C. granulomatis* have been observed using a complement fixation method in sera from patients whose lesions persisted for more than three months. More recently, a successful indirect immunofluorescence technique has been described. Sera from patients are applied to biopsy tissue sections containing Donovan bodies and treated with antihuman IgG conjugated with fluorescein isothiocyanate. In the absence of culture methods or reliable and simple nonculture detection tests, this serological assay may prove valuable for the diagnosis of donovanosis.[77]

CANDIDIASIS

Vulvovaginal candidiasis is caused by *Candida albicans* in approximately 85 percent of cases, with the remaining cases caused by other species, particularly by *C. glabrata.*[78] Classic clinical symptoms and signs of candidiasis include vaginal itching, vulvar burning, external dysuria, curdy white discharge (that looks like cottage cheese) without malodor, and erythema of the labia and vulva. Symptoms and signs, however, are often less specific, and laboratory diagnosis is essential for accurate differential diagnosis.

Direct microscopy

The yeast form is easily recognized in a wet mount preparation of vaginal fluid as round to ovoid cells of 4 μm diameter with typical budding. Adding a drop of 10 percent KOH to the preparation may facilitate the detection of yeast, in particular the recognition of mycelia (pseudohyphae). Yeast is Gram-positive and can easily be observed in a Gram-stained smear. The sensitivity of a wet mount, however, is superior.

Culture

Culture remains the most sensitive method currently available for the detection of *Candida.* However, it should be stressed that a positive culture does not necessarily indicate that *Candida* is responsible for vaginal symptoms, as more than 20 percent of healthy women may harbor *Candida* in the vagina. Microscopy has a much higher diagnostic value. Few patients with symptomatic vaginal candidiasis have negative microscopy. Consequently, culture may only be useful if vaginal candidiasis is clinically suspected in the presence of a negative wet mount preparation.[79]

Colonies of yeast appear after one to two days' incubation at 36°C and are white opaque to creamy. The only important identification of isolates consists of microscopic differentiation from bacteria. Additional confirmation is not essential for routine diagnosis of vaginal candidiasis.

TRICHOMONIASIS

Trichomoniasis is considered mainly sexually transmitted. Nonvenereal acquisition through fomites may be possible, but is not well documented. *Trichomonas vaginalis* elicits an acute inflammatory response resulting in vaginal discharge containing large numbers of polymorphonuclear neutrophils. Typical symptoms associated with trichomoniasis include vaginal itching or irritation and frothy gray to green-yellow discharge. Vaginal malodor and dysuria may be present.

The infection is caused by *Trichomonas vaginalis,* an ovoid, globular, pear-shaped flagellated protozoan. Although certain symptoms and signs are predictive for trichomoniasis, visualization of the parasite is required to establish the diagnosis.[80]

Direct microscopy

Trichomonads are easily recognized in a wet mount preparation of vaginal fluid by their typical jerky motility. An increased number of polymorphonuclear leucocytes is usually observed, but small numbers of leucocytes do not rule out infection.

Other diagnostic methods

Culture of *T. vaginalis* is currently the most sensitive method for diagnosing trichomoniasis and may be recommended when vaginal infection is suspected despite negative wet mount results, for diagnosis of trichomoniasis in men, and for research.

Various direct detection methods for *T. vaginalis,* including immunofluorescence, latex agglutination and enzyme-linked immunosorbent assay, have been described. A recently developed antigen immunoassay seems to be comparable in sensitivity and specificity to culture.[81] Several methods for antibody detection against *T. vaginalis* in serum and in vaginal washings have been evaluated but did not contribute to a more adequate diagnosis of trichomoniasis.

Bacterial Vaginosis

Bacterial vaginosis (BV) is a clinical entity characterized by slightly increased quantities of malodorous vaginal discharge. It is associated with an overgrowth of the normal bacterial flora of the vagina with *Gardnerella vaginalis, Mycoplasma hominis* and various anaerobic bacteria, such as Bacteroides and Mobiluncus species.

Diagnostic procedures

The diagnosis of BV is based on the presence of at least three of the four following characteristics:[82,83]

Homogenous white-gray adherent discharge: Interpretation of this clinical sign is subjective. Discharge seen in women with BV is often not markedly increased over that seen in healthy women; the application of vaginal douches may reduce the amount of discharge.

Increased vaginal pH: The normal mature vagina has an acid pH of ±4.0. In BV, the pH is generally elevated to more than 4.5. The vaginal pH test has the highest sensitivity of the four characteristics, but the lowest specificity. An elevated pH is also observed if vaginal fluid is contaminated with menstrual blood, cervical mucus or semen and in *T. vaginalis* infection.

Malodor: Women with BV often complain of vaginal malodor, which is due to the release of amines produced by anaerobic bacteria that decarboxilate lysine to caverdine and arginine to putrescine. If a drop of 10 percent KOH is added to the vaginal fluid, the amines immediately become volatile, producing a typical fishy amine odor.

Presence of clue cells: These cells are squamous epithelial cells covered with many small coccobacillary organisms. Microscopy of a wet mount shows stippled granular cells without clearly defined edges because of the large numbers of adherent bacteria present and an apparent disintegration of the cells. The adhering bacteria are predominantly *G. vaginalis,* sometimes mixed with anaerobes.

Additional laboratory tests

A Gram stain of a vaginal smear has a higher specificity for the detection of clue cells than a wet mount preparation. Moreover, a Gram stain allows good evaluation of the vaginal bacterial flora. Normal vaginal fluid contains predominantly Lactobacillus species and exceedingly low numbers of streptococci and coryneform bacteria. In BV, lactobacilli are replaced by a mixed flora of anaerobic bacterial morphotypes and *G. vaginalis.* Culture of bacteria associated with BV, however, is not essential for routine diagnostic purpose.

DIAGNOSTIC NEEDS

STD control programs are hampered by difficulties in diagnosing STDs. Many infections are asymptomatic, particularly in women, and even when symptomatic, may have different etiologies. Although combined therapy can be used effectively, simple, inexpensive tests are urgently needed, particularly for *N. gonorrhoeae* and *C. trachomatis* infections in women. Simple, inexpensive diagnostics are also necessary to identify the different causes of genital ulcers. High-quality, sturdy microscopes, centrifuges, rotators and other essential equipment that will provide years of services should be available at low cost.

The ideal diagnostic test would be:

- **Accurate**—highly sensitive and specific
- **Inexpensive**—affordable in developing countries
- **Simple**—requiring minimal training and uncomplicated or no equipment
- **Rapid**—with results available before a patient leaves the clinic (maximum 20 minutes)
- **Convenient**—so that specimens are simple to collect and socioculturally acceptable (do not require venipuncture or vaginal speculum examination, such as saliva, urine, vaginal swab or capillary blood)
- **Stable**—using reagents with long shelf life that require no refrigeration (35°C and 80 percent humidity)
- **Functional**—packaged simply with easy instructions

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CHAPTER 13

Innovative Approaches to STD Control

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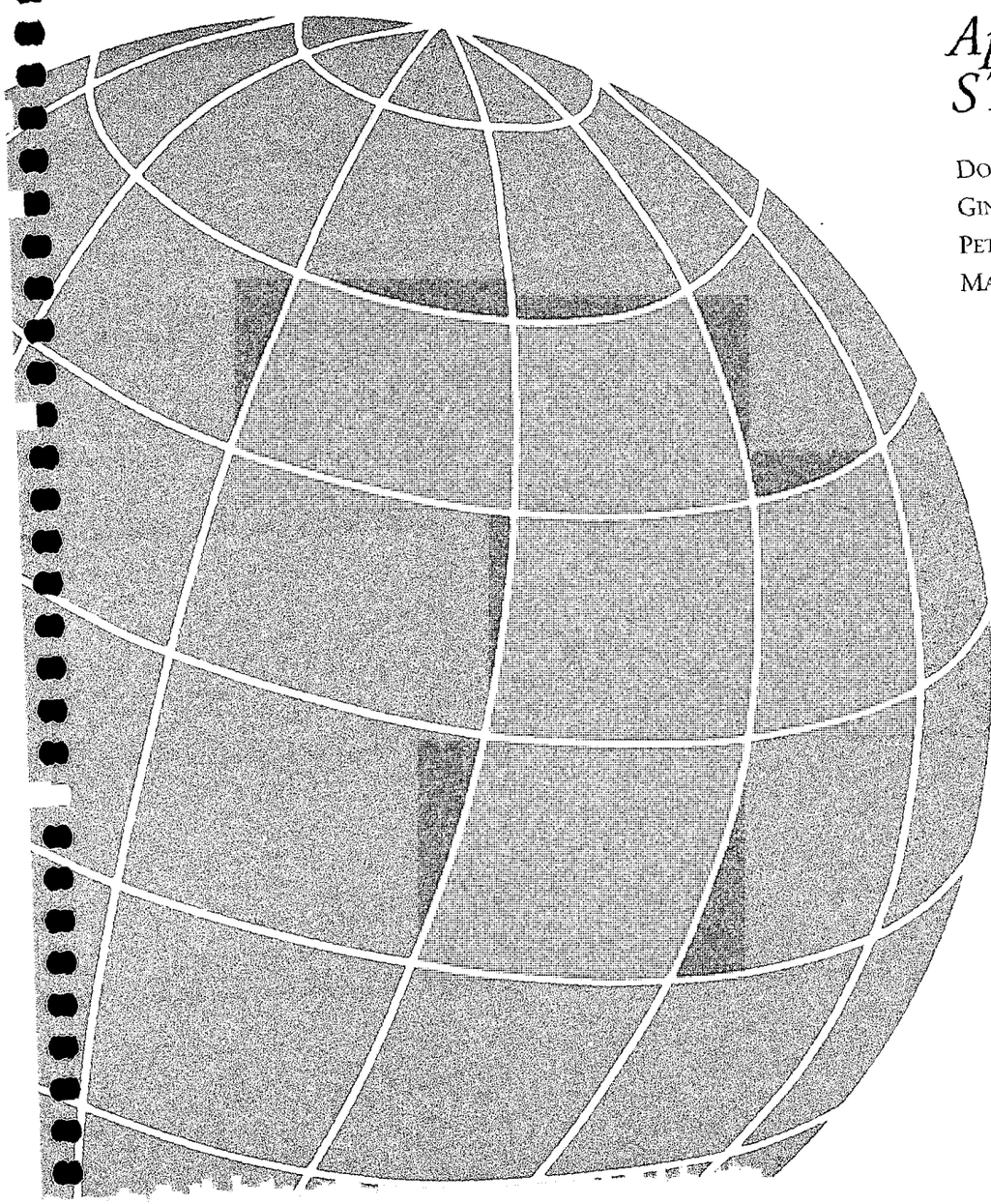

preview CHAPTER 13

Innovative Approaches to STD Control

INTRODUCTION

This chapter provides information about how to implement more effective approaches to STD control. Although some of the proposed interventions are not new, most have not been fully tested or accepted by the medical and scientific communities.

KEY CONCEPTS AND ISSUES

The concepts of targeting, improved treatment-seeking behavior and effective treatment at the point of first encounter are key in designing interventions that will have the greatest public health impact.

TARGETING STD SERVICES TO PRIORITY GROUPS

These groups include sex workers, persons working away from home and youth. Brothel-based STD services, mobile vans, workplace and peer education programs are examples of strategies to reach them.

APPROACHES TO MANAGEMENT

Discussion focuses on clinical management, screening and case finding, partner referral and treatment, and empiric prophylaxis/treatment.

The last strategy, **prophylaxis/treatment,** involves giving periodic treatment to everyone in the target group regardless of symptoms. Although it has not been studied extensively, it is recognized as useful particularly when clinic access is poor and behavior change at the individual and community levels might not result in a rapid STD decline.

IMPROVING STD HEALTH-CARE-SEEKING BEHAVIOR

Since the success of efforts depends in part on cultural attitudes and perceptions, ethnographic research can help managers design community-appropriate programs. To this end, a tool has been developed, Targeted Intervention Research (TIR), which assists managers in designing and conducting formative research on STDs.

TREATING STDS IN WOMEN: INTEGRATION OF STD SERVICES INTO BROADER REPRODUCTIVE HEALTH SERVICES

Integration of STD services into broader reproductive health services could enhance their acceptability and effectiveness. However, this approach is less likely to reach adolescents, single, sexually active women, including female sex workers, and women who have completed childbearing. The integration concept is new, and many pilot programs will need to be implemented before the appropriate measures of success are available.

THE PROBLEM OF SELF-MEDICATION

Two approaches to self-medication have been field-tested in demonstration projects. One approach is to train pharmacy workers in syndrome management; the other is to promote syndrome-selective packages containing effective drugs and prevention materials. Both hold promise and await further evaluation.

CONCLUSION

STD service infrastructure are either weak or nonexistent in most developing countries. Building them is essential for long-term STD control. In the meantime, concomitant interventions are needed that can be implemented immediately and achieve a rapid reduction of STDs. These innovative interventions must be able to work with what is available in terms of existing resources and infrastructures.

INTRODUCTION

The previous chapters have described the different components and support services that are required for STD prevention and control, and have addressed many of the programmatic issues involved. It is important to recognize that many aspects of the STD control model of specialized treatment and referral centers developed in industrialized countries may not be appropriate, feasible or transferable to many resource-poor settings. There patients, particularly males, commonly seek STD treatment outside the formal sector and STDs are treated along with a multitude of other health problems by primary health-care workers who have received little or no specific training in STD management.

In addition, STD control in these settings must compete for resources with other important and less stigmatized health problems. Although funding for STD control has increased as a result of HIV/AIDS control programs, resources are still inadequate and health infrastructures remain weak. Given the urgency of the task at hand, more innovative approaches must be developed and implemented.

This chapter will explore a number of innovative approaches to STD control. No approach presented is really new. A few are borrowed from other fields and are only innovative in their application. Others are innovative in that they legitimize and standardize current practices that are not well accepted by much of the traditional and conservative medical and scientific communities. Some others recruit and engage providers from the informal sector as new partners in STD service provision. They are pragmatic approaches to which we must be open, and bold enough to consider and field-test.

KEY CONCEPTS AND ISSUES

In designing interventions that will have the greatest public health impact, the concepts of targeting, improved treatment-seeking behavior and effective treatment at the point of first encounter are key. The rationale for these strategic concepts and the programmatic issues that arise in operationalizing them are discussed below.

IMPORTANCE OF TARGETING

Not all members of a population are at equal risk for acquiring or transmitting STDs. Relatively small groups of community members known epidemiologically as "core groups" or "high frequency transmitters" are responsible for sustaining and perpetuating the spread of STDs in a community.[1-4] Targeting limited resources to these priority groups will have a much greater impact on STD prevalence in a community than programs aimed at the general population.[5]

Challenges in making this concept operational are twofold. First, it can be difficult to identify and access these core groups. Second, it is important not to stigmatize or ostracize them while they are receiving prevention and care services. Although behavioral, ethnographic and epidemiologic surveys defining these core groups are often lacking, experience has shown that sex workers and their clients, people working away from home (e.g., migrant workers, long-distance truck drivers and military personnel) and youth often have high rates of STD infection. In addition, urban populations generally have a higher prevalence of STD infections than rural ones.

TREATMENT-SEEKING BEHAVIOR

In many developing countries, the point of first encounter for STD self-medication and treatment is in the informal health sector. Over the counter purchase of antibiotics at pharmacies (drugstores or chemist shops) or from drug vendors and injectionists is almost universal despite laws that regulate their distribution. The treatment obtained from these sources is frequently inadequate or ineffective, patients do not receive the benefit of prevention education including condom advice and their sexual partners are not referred or treated.

- In Cameroon, a survey of men leaving pharmacies found that only 9 percent of men in Douala and 15 percent of men in Yaoundé received their prescription from a medical doctor.[6] The majority received their prescriptions from pharmacies, 38 percent and 54 percent, respectively. Pharmacists were the source of the prescription in 7 percent and 9 percent of the cases, respectively. The next most common source of advice was from friends, family or self, 46 percent and 21 percent, respectively. A total of 50 percent to 75 percent of the patients were treated incorrectly. The more "medical" the initial visit the higher was the cost of prescribed treatment.

It can be argued that in most developing countries, STD patients are not likely to receive more effective or comprehensive management in the formal clinic sector. This is generally due to scarce resources, limited provider training and the demands of patient flow and/or profit that often preclude any prevention education.

Although much research is needed on the determinants of STD care-seeking behavior, a number of barriers exist to seeking care in the formal sector. These include the following: the cost of long waiting times and return visits required for laboratory results; treatment failures and drug refills; the cost of transportation, consultation fees, laboratory tests and prescriptions; and the social implications of being seen in an STD clinic where staff are often judgmental, and privacy and confidentiality are often lacking.

These financial and social barriers apply particularly to women, and improving their access to and use of STD services is a major challenge in STD control. There is a low specificity or absence of clinical manifestations when women are infected with an STD.[7] A large number of women do not recognize some STD symptoms as abnormal.[8, 9] Finally, diagnostic tests for reproductive tract infections are not readily accessible.

Effective Management at the Point of First Encounter

A patient's first encounter with the health-care system may be the only contact, and it is likely to affect future treatment-seeking behavior, partner treatment and the treatment's cost-effectiveness. Therefore, STD management at that initial point should be as comprehensive and effective as possible. This first encounter might be in the public or private sector, in the formal or informal sector, at a central specialized clinic or a peripheral primary health-care clinic such as a maternal child health (MCH) or a family planning (FP) clinic.

Most of these providers do not have access to adequate examination or laboratory facilities. The use of standardized flowcharts based on the syndrome management approach *(see Chapter 8)* will enable them to make a diagnosis and manage the patient effectively. Key issues in improved care, discussed in detail in this handbook, include the availability of effective drugs, provider attitudes toward patients, privacy and confidentiality issues, provision of prevention services (condoms, education about risk reduction and therapy, and partner referral) and curative services.

Targeting STD Services to Priority Groups

At times it can be difficult to identify and access "core groups," and behavioral, ethnographic and epidemiologic information defining them is lacking. Nevertheless, three broad sub-populations in most communities warrant specific services because of their high prevalence of STDs. These three groups are sex workers, persons working away from home and youth. The discussion below will focus on services that have been piloted or proposed to reach these groups. The sustainability, cost and ultimate impact of these interventions have not been evaluated. Naturally, these will depend on STD prevalence in the target population, the effectiveness of the curative and preventive services, and the number of people within the target population covered.

Sex Workers

In designing STD services for sex workers, the main challenge is to target without stigmatizing. If sex workers are going to use services, they must feel comfortable, safe and confident about them. Confidentiality and privacy must be ensured, and service hours must be convenient. This can best be accomplished by involving members of this community in designing the services.

Regular screening of registered sex workers, often a legal requirement, is performed in several countries. However, these services are often stigmatizing and of little public health value since screening tests are either inappropriate or inadequate. Sex workers generally view such services as a legal hurdle rather than a health benefit. Furthermore, this approach does not reach unregistered or "clandestine" sex workers, a group that may be at higher risk for STDs than registered sex workers. In a study recently conducted in the Philippines, the prevalence of gonorrhea among unregistered female sex workers was 37.8 percent compared to 7.2 percent among registered ones.[10]

Brothel-based STD services have been piloted in Tanzania, Mali, Côte d'Ivoire and India. This approach applies to areas where brothel-based sex workers are

prominent. Sex workers prefer these services because they are available at convenient hours and are private and confidential.

- In many countries in Asia such as Thailand, Indonesia and the Philippines, commercial sex establishment owners contract private practitioners to provide regular (usually weekly or biweekly) on-site STD check-ups and treatment of their employees.[11]
- In Tanzania, four types of STD services for sex workers were compared; brothel-based periodic visits; clinic visits outside normal hours; regular clinic attendance at upgraded clinics; and regular clinic attendance at clinics without intervention. Sex workers preferred brothel-based STD services. However, STD services at clinics outside the normal operating hours were more acceptable than STD services offered during normal clinic hours.[12]
- In Mali, a visiting medical team regularly provided care to sex workers on site at the brothel during hours that did not interfere with the women's work. Almost all of the women agreed to be examined. To avoid stigmatization, the team traveled by public transport and taxi rather than by government and project vehicles, which would have been conspicuous.[13]

Mobile vans providing care and prevention services have also been used to reach sex workers.

- In Tamil Nadu, India, numerous surveys by nongovernmental organizations (NGOs) considering the use of ambulatory clinic vans have shown that sex workers generally work in areas far away from their homes and prefer to live anonymously in their own neighborhoods. A neighborhood clinic, either fixed or mobile, which only provides STD services, would probably draw too much attention from other neighbors. It is unlikely that sex workers would use them for fear of being labeled. These women prefer to seek STD treatment outside their communities or in clinics that cater to the entire family and provide a broad range of primary health services.[11]

Clinic-based interventions offering either specialized or integrated services have been tried in many countries. Integrating STD services into other basic health services, primary care, FP and MCH services, can reduce the stigma attached to specialized STD clinics as long as health-care providers are nonjudgmental and treat the sex workers with respect.

- In Kinshasa, Zaire, a special women's health center was established in an area where many sex workers lived.[14] The clinic provided health education, free STD treatment and free condoms. The study demonstrated that a clinic-based intervention of care and prevention can reduce the incidence of STD and HIV. It was also noted that once the women realized they were receiving quality services they were more receptive to prevention messages, creating a "care-prevention synergy."[15]
- Based on an assessment of the target community's needs in the Sonagachi district of Calcutta, India, a health service center for sex workers and their families was opened at a local youth club in the heart of the "red light" area. Although the emphasis is on sexual health, other basic health services are also provided. Effective STD treatment coupled with peer education and a condom distribution program has resulted in a reduction of STD prevalence in the community, dropping from 80.6 percent to 59.2 percent over three years.[16]
- In Nairobi, Kenya, a small storefront clinic providing family planning services to high-risk women in the neighborhood instituted STD care services at the request of the health-care workers. A revolving drug fund was established and community-based distributors of contraceptives were trained to refer symptomatic women to the clinic.[17]
- In Bharatpur, Nepal, and Madras, India, demonstration projects are planned by the Family Planning Association of Nepal and Parivar Seva Sanstha, respectively, to determine whether STD services can be successfully provided to female sex workers through family planning clinics.[11]
- In Tanzania, facilities offering STD services integrated into primary health-care services (PHC) were the least preferred source of care among sex workers along truck routes. The sex workers preferred care at their brothels or in the clinics at hours different from the normal clinic hours.[12]

- In Côte d'Ivoire, surveys on health-care seeking behavior among sex workers indicated that services delivered close to the work site were desired. A special clinic to provide STD care was established in the area and peer health educators, trained about safe sex and condom use, referred women to these clinics.[15]

Private clinics or private practitioners are the choice of many sex workers even if they are required to use government clinics for legal purposes. In some cases, such as in the Philippines, sex workers will first go to a private practitioner to ensure a clean bill of health before next visiting the government social hygiene clinic.[18] In the Dominican Republic, sex workers visit private practitioners when symptomatic to ensure that any potential STDs are treated, even though there is a requirement for regular check-ups in the government clinics.[13]

- In Haiti and Nepal, efforts are now underway to identify a core of private practitioners that currently provide or are committed to providing services to sex workers. The practitioners will be targeted with printed information and receive training on STD management for sex workers.[11,19]
- It has been proposed that coupons or vouchers be provided to sex workers that could be used in selected clinics or with selected private practitioners. Sex workers would then be eligible for discounted, expedited or free treatment.

Peer health educators and outreach workers are often used to provide face-to-face prevention information to hard-to-reach populations *(see Chapter 4)*. In STD control, peer health educators have been used to encourage symptomatic individuals to seek care and to provide them with information about where it can be located.

- In Tanzania, peer health educators at truck stops, who were already involved in condom promotion and HIV risk reduction education, were trained to assess risk using three simple questions.[20] An affirmative answer to any of the three questions was supposed to prompt the peer educator into referring the woman for treatment. However, the peer health educators were unable to apply the score properly, even after repeated training. It was surmised that the educators were important for their role in encouraging the women to seek care, but in this pilot project they were unable to refer women at higher risk based on a risk score. [21]
- In Madras, India, the AIDS Control and Community Education Programmes Trust has started an outreach program for sex workers in the central train station area. Sex workers with STD complaints are being referred with a letter to the public hospital for free treatment. The referral letter helps to ensure that the women are treated well by the clinic staff. So far the women appear to be pleased with the services and with the attitude of the staff whom they have encountered.[22]

Persons Away From Home

Persons away from home for long periods may be at increased risk for STDs because their work takes them outside their normal social settings and support systems. As noted previously, this target population typically includes truck drivers, military personnel, and workers at large construction, mining or agricultural sites in remote areas. Although basic health services are often offered to these workers by their employers, many are forced to seek STD care elsewhere to avoid undesirable job repercussions.

There are many challenges and opportunities in providing care to these groups. They include building advocacy among company managers so they will allocate resources for STD prevention and control in the workplace; ensuring that the confidentiality and privacy of the employees are maintained; and making sure that employees have access to high-quality and socially acceptable STD services.

The following are some examples of ways to reach these groups:

- In Tanzania, STD treatment and prevention services were provided to truck drivers and their families at the main company headquarters in Dar Es Salaam.[23] Peer health educators were also trained to encourage early treatment as well as other STD and HIV prevention activities.
- In Tamil Nadu, India, in a project overseen by the AIDS Research Foundation of India, an arrangement has been made for two private practitioners to provide STD services to the men at three project sites. The men pay for the prescribed medication, but the project pays a set consultation fee. The men are told that a third party is paying for the consultations.[24]
- In India, a mobile STD clinic mounted on a van for truck drivers along the Madras-Bangalore highway is being considered by a local NGO.[24]
- In Kenya, Senegal and Nigeria, policy work is being done with company managers to convince them to allocate resources for HIV prevention, including STD management, using the Private Sector AIDS Prevention Package (PSAPP).[25]
- In Malawi, assistance is being provided to companies and agricultural estates that have their own health clinics to ensure that health providers are properly trained in STD management using syndrome diagnosis, and to optimize appropriate STD drug procurement.[26]

The suggestion has been made to require the provision of STD/HIV prevention activities, including care and management, when large public works projects such as dam or road construction are planned. In these transient communities, with men separated from their families for long periods of time, contact between laborers and sex workers increases.

Adolescents

Adolescents have unique reproductive health needs. They need access to convenient, user-friendly, confidential, low-cost STD care and contraceptive services. In general, adolescents have limited information and skills for making responsible sexual decisions. Female adolescents are biologically more susceptible to some STDs because of an increased zone of ectopy and because of other genital tract characteristics due to the hormonal changes of puberty.[27]

There is limited experience regarding the kind of reproductive health services to provide to adolescents, how to provide them and how cost-effective they are. Current efforts to integrate STD services into broader reproductive health services are unlikely to have a large impact on this population.

The following includes a few examples of how young people are being targeted:

- In Colombia and Swaziland, UNICEF is developing youth centers or special care units within existing care facilities, with specific days for youth. These centers and units will provide comprehensive health-care, including STD care and family planning services.[28]
- In Guatemala, Asociación Pro Familia (APROFAM) offers STD services to adolescents at the "El Camino" youth center it runs in Guatemala City. In addition to clinical services and sex education, the center provides social and educational services (vocational workshops) as well as cultural and recreational activities. Clinical services include general medicine, gynecology, pre- and post-natal care, family planning and psychological counseling. Most of the services are free.[11]

APPROACHES TO MANAGEMENT

Approaches to managing STDs in both symptomatic and asymptomatic high-risk individuals are reviewed in this section. The discussion focuses on clinical management, screening and case finding, partner referral and treatment, and empiric prophylaxis/treatment.

Clinical Management

The use of standardized STD flowcharts based on the syndrome management approach *(see Chapter 8)* will enable the majority of providers, who generally lack access to adequate examination or laboratory facilities, to manage symptomatic patients effectively. The syndrome management approach to STD care is patient-centered, rapid and effective, in marked contrast to the classic dermato-venereology approach. Treatment can be provided during the initial visit, which reduces the risk of further spreading the infection, and the risk of sequelae developing from untreated infections. In addition, the need to return for laboratory results is eliminated. Because there are no lab expenses, there are cost savings. And since treatment covers all major pathogens, there are fewer treatment failures.

Women represent a major challenge in STD control *(see "An Approach to STDs in Women: Integration of STD Services into Broader Reproductive Health Services")* primarily because of the low specificity, or absence, of clinical manifestations when they are infected. The validity of syndrome-based flowcharts for lower genital tract infections in women is not optimal, and laboratory tests remain essential for detecting STDs in asymptomatic and high-risk women.

Screening and Case Finding

Screening and case finding are limited by the availability of validated tools and diagnostics. The use of diagnostic tests for screening purposes is limited by cost, the need for laboratory capabilities and by logistics.

By instituting clinic-based screening, antenatal clinics in Kenya were able to dramatically increase the number of women who were screened for syphilis with a rapid plasma reagin (RPR) and treated. This allowed them to bypass many of the logistical problems of sending specimens to the lab, waiting for results and asking the women to return[29] *(see Chapter 9)*. Several research groups are evaluating whether a risk assessment based on behavioral characteristics could be developed to screen asymptomatic women for STDs. The current risk score recommended by WHO was developed for the management of symptomatic women *(see Chapter 8)*. The development of an inexpensive simple bedside diagnostic test for gonorrhea and chlamydial infection in women is now a research priority for several international health organizations.[30]

However, risk assessment and diagnostic tests are not mutually exclusive approaches to asymptomatic infections. A region in the United States successfully used risk assessment on asymptomatic women to identify those who would undergo a diagnostic test for chlamydia.[31] The use of the risk assessment prior to testing made the screening more cost-effective.

Partner Referral and Treatment

Partner treatment is an underutilized and understudied approach to STD control *(see Chapter 11)*. In the U.S., a pilot project is underway to determine the effectiveness of sending the index patient home with therapy for the partner(s).[32] Furthermore, in settings that lack the capacity to perform screening tests, partner referral/notification of symptomatic men offers an opportunity to identify and treat women who are asymptomatic or otherwise unaware of their infections.

Empiric Periodic Prophylaxis/Treatment

Empiric periodic prophylaxis/treatment of selected STDs among high-risk groups (often referred to as mass treatment) is a much discussed yet little studied strategy to achieve a rapid decrease in a community's reservoir of STDs. This strategy involves giving periodic treatment to everyone in the target group regardless of symptoms. Depending on the pharmacokinetics of the drug used, periodic administration of antibiotics may treat an existing infection or act as a prophylaxis against a potential infection.

Strategies to rapidly reduce a community's pool of sexually transmitted infections are desirable for the following reasons: (1) sexual behavior changes at the individual and community levels are likely to take time and therefore not result in a rapid STD decline; (2) many patients are asymptomatic or the symptoms are too mild to trigger treatment-seeking behavior; (3) having symptoms does not necessarily lead to treatment-seeking behavior; and (4) even with behavior change, some groups may continue to have relatively high levels of STDs. In addition, with the following problems, empiric treatment/prophylaxis may be more feasible than the existing delivery systems:

- **Access**
  Clinical services are either unavailable or unavailable at appropriate hours.
- **Use**
  High-risk individuals may be asymptomatic or avoid using services due to issues of stigmatization, provider attitudes, cost, punitive consequences or other barriers.
- **Quality of services**
  Clinical services may be inadequate for diagnosing and managing STDs, particularly for women for whom physical examination and testing require some degree of infrastructure.
- **Sensitivity of detection methods**
  Existing sensitivity for diagnostic tests (chlamydial infection) or physical examination (genital ulcers in women) may be low.
- **Compliance**
  People who come for testing may not come for treatment.

Empiric treatment or mass treatment was used by the World Health Organization and the United Nations Children's Fund to control and eradicate yaws and endemic syphilis in the 1950s and 1960s.[33] This program resulted in a dramatic reduction in the number of cases of yaws and endemic syphilis. However, since then there has been an increase in the number of reported cases because a permanent treatment and control program was never established.

There have been a handful of reports addressing the issue of empiric, periodic prophylaxis or treatment of groups for STDs, including the following:

- Greenland attempted a community-based mass treatment for gonorrhea, supplemented by mass laboratory examinations and contact tracing during the late 1960s.[34] The prevalence of gonorrhea was reduced by 50 percent among those examined in the towns and by 75 percent among young people in rural areas. However, this intervention was expensive and ultimately not sustainable, and pre-intervention levels of gonorrhea were seen within three to six months after the program was discontinued
- In 1967, mass antibiotic treatment with oral ampicillin and probenecid or tetracycline was given for gonococcal infection to 4,000 female sex workers in Olangapo, Philippines, over a one-week period.[35] The intervention was attempted after weekly culture and treatment of sex workers had lowered the prevalence of gonorrhea in the sex workers from 11 to 4 percent. After the mass treatment, the prevalence of gonorrhea fell to 1.8 percent. However, this low level was not maintained and within one month of the intervention it rose to the pre-treatment baseline. It appeared that the single empiric mass treatment did little to diminish the prevalence of gonorrhea in a setting where there was already a strong program for its control.

- In Surabaya, Indonesia, sex workers have received penicillin treatment since 1957.[36] The prevalence of reactive syphilis serology measured by nontreponemal screening tests has dropped from 87 percent in 1957 to 1.5 percent in 1992 among registered sex workers, and from 86.6 percent in 1957 to 4.2 percent in 1992 among street-based sex workers. Yaws was endemic in Indonesia until the mass treatment campaigns of the 1950s and 1960s and is likely to be reflected in the earlier serologies. Nonetheless, the persistently low prevalence of syphilis in these sex workers suggests that empiric therapy for syphilis might be effective. The appropriate dose and treatment interval have not been defined.
- In Fresno, California, in response to an explosive increase in syphilis cases in the mid-1970s, a selective mass treatment campaign against syphilis and gonorrhea was introduced for 12 months as part of a syphilis control program.[37] Sixty percent of the cases had occurred among sex workers and seasonal farm workers. In addition to this selective mass treatment program for sex workers, longer clinic hours were established, making the clinic more accessible to sex workers and migrant farm workers. In addition, a migrant outreach program providing STD services to farm workers in a mobile van was introduced. Syphilis cases declined among sex workers, farm workers and other men and women. Because mass treatment was only one of several control program elements, it is not possible to know the extent to which it brought about the decline in syphilis. The long-term impact of the campaign was not reported.
- In May 1981, in response to an outbreak of chancroid among Hispanic men and sex workers in Orange County, California, a one-day, door-to-door educational campaign was conducted in the ten neighborhoods with the largest clusters of cases.[38] Individuals with the potential for the disease were encouraged to attend the municipal STD clinic. All clinic patients with genital ulcer disease and a history of contact with a sex worker, as well as their partners and all sex workers, were presumptively treated for chancroid. These control measures seemed to bring the chancroid outbreak under control.

The impression from these few studies is that empiric prophylaxis/treatment was successful in controlling STD outbreaks of syphilis and chancroid when it was combined with other control efforts such as community outreach, targeting and contract tracing. The Subic Bay, Philippines, experience demonstrates that a reduction in the prevalence of gonorrhea cannot be sustained after a single empiric treatment/prophylaxis event or when the periodicity of the intervention cannot be maintained at a sufficiently short interval to keep up with the rate at which the target population is getting reinfected. The Greenland experience corroborates the Subic Bay experience and demonstrates that empiric periodic treatment/prophylaxis for gonorrhea can be prohibitive because reinfection rates can be very high. Although complicated by the lack of specificity of non-treponemal tests, the persistently low prevalence of positive syphilis serology in Indonesian sex workers suggests that the intervention might be effective. Overall, this data also suggests that diseases with a long duration of infection such as syphilis, chancroid or chlamydial infection may be more amenable to control with this approach than short duration diseases such as gonorrhea.

The effectiveness of empiric prophylaxis/treatment can be greatly enhanced by concomitant behavior change and condom distribution interventions. This empiric prophylaxis/treatment approach might be regarded as a short-term intervention complementing the longer-term solutions of primary prevention and clinic-based services. Data from commercial sex workers in Nairobi, Kenya, in 1985 indicated that the mean time to reinfection with gonorrhea was 12 days and the weekly incidence of gonococcal infection was 11 percent.[39] These data suggest that the cost of mass treatment can become prohibitive if the reinfection rate is high.

Empiric periodic prophylaxis/treatment of selected STDs can be conceptualized for individuals, communities, general populations or for selected high-risk populations. Criteria that might be considered when deciding which populations to target and what disease(s) to direct therapy against include the following:

The population

- Access to targeted populations
- Acceptability of the approach to target population
- Population compliance

The pathogen(s)

- The disease's prevalence in the population
- The reinfection rate in the population
- The population's risk for HIV
- The therapy (preferably one that is highly effective against the selected pathogen(s), and is given in a single dose, orally administered and has few side effects)
- The likelihood and severity of complications if left untreated
- The duration of infectiousness
- The difficulty in diagnosis (this may be different by sex)

The program

- Intervention sustainability
- Marginal yield of empiric prophylaxis/therapy compared with standard control measures
- Cost-effectiveness (the cost effectiveness will decrease as the prevalence of the disease falls)
- The presence of a comprehensive STD/HIV prevention program that includes behavior change interventions, condom promotion and other alternate ways to access STD care

There are several potential risks associated with this empiric prophylaxis/treatment approach and with the widespread use of antibiotics that need to be weighed. On the individual level, the efficacy of the antibiotic in treating the current infection and the potential risk of re-exposure with sub-therapeutic levels of the antibiotic need to be examined. Exposure to sub-therapeutic levels could lead to increased antibiotic resistance. Routine antibiotic use might disrupt the mucosal barrier of the normal flora and, in turn, increase the risk of certain diseases. For example, altering the pH of the vagina or eradicating peroxide-producing lactobacilli may increase susceptibility to HIV infection. A change in the vaginal flora also may increase the risk of vaginal candidiasis. Other potential risks include adverse drug reactions and the possibility that unsterilized needles will be reused.

Some epidemiologists would argue that empiric periodic prophylaxis/therapy also may have the effect of increasing higher-risk sexual behavior. It is possible that this approach may affect the number of partners (including those at high risk), the frequency of sexual activity and the frequency of condom use. There have been no studies that address these issues.

On the community level in developing countries, many of the antimicrobials that could be useful for empiric prophylaxis/therapy (fluoroquinolones, third generation cephalosporins and long-acting macrolides) are also used to treat other major diseases. Routine application of these drugs may render them useless in treating such serious diseases such as salmonella, shigella and tuberculosis. In the Rakai district of Uganda, a population-based mass STD treatment trial is underway.[40] The study will address some of the issues just outlined and is being watched with great interest.

APPROACHES TO IMPROVING STD HEALTH-CARE-SEEKING BEHAVIOR

Several approaches are being taken both to understand and improve the treatment-seeking behavior of symptomatic individuals. They are discussed below.

PROGRAM-DRIVEN ETHNOGRAPHIC RESEARCH

It is now well-recognized by public health specialists and social scientists alike that pre-program research (formative research) combining qualitative and quantitative methodologies is required to design and implement programs successfully. Since the community perception of STDs is often quite different from the medical one, STD control managers must first understand the community's perspective before designing STD programs. This ensures that programs meet the perceived needs of community members in a way that is acceptable to them.

A tool has been developed, referred to as Targeted Intervention Research (TIR),[41] which assists program managers in designing and conducting formative research on STDs, to ensure maximum relevance to program design and implementation.

The TIR is a set of instruments that helps uncover health-seeking behavior as it relates to clinic-based STD programs and complementary health education activities designed to increase STD knowledge and demand for services. The instruments also try to identify barriers to condom use and ways to increase condom availability in the community. From the community perspective, the instruments address sexually transmitted illness-related concepts and practices, illness management, service delivery, gender specificity, partner notification, post-treatment practices, and communication and prevention issues.

The methodology includes establishing a multidisciplinary technical advisory group of social scientists, communication experts, clinical experts and public health officials who will assist in identifying research priorities and guide the research.

- In Malawi, for example, researchers found that many of the illnesses mentioned by the people who were interviewed closely matched western biomedical definitions of STDs. For some STDs, however, the early and late stages of an infection were considered separate illnesses and were given different names and treatments. An understanding of such distinctions can help STD care providers improve communication with their clients.[42]
- In Zambia, in contrast to expert informants who felt sure that local language easily discriminated between such common STDs as syphilis and gonorrhea, it was found that there was a great disparity between local language and biomedical terms.[43] It was recommended that all communication messages refer to symptoms rather than to disease names.
- In Ethiopia, getting care from a government health clinic was often the last recourse for therapy. Reasons cited by community members included the stigma of an STD-only examining room in the clinic, long waiting times, condescending and judgmental providers and the lack of privacy during the consultation.[44]
- In the Philippines, sex workers from Manila and Cebu City cited condom use, careful partner selection and examination of partner genitals as methods for preventing STDs. Undergoing a clinical examination to detect and treat STDs was not mentioned.[45]

INCREASING WOMEN'S AWARENESS OF STDS

Educating women to recognize abnormal symptoms will increase the number of women seeking care. As long as resources are available to adequately detect, diagnose and treat STDs, the following approaches to improving STD treatment-seeking behavior in women might be considered.

- In Thailand, community workers instruct women on how to recognize abnormal symptoms and potential risk factors. This approach is now being evaluated.[46]
- In Bangladesh, camps were set up to determine the magnitude of STDs in the communities, provide STD and HIV education, and raise awareness of STD symptoms and risk behavior. At three different

health posts in a Bangladesh city of more than 100,000 inhabitants it was found that women were fourteen-times more likely than men to attend the camps; this may reflect the fact that the camps had previously been used in family planning programs. Although at least half of the women were found to have a history or a physical examination suggesting a reproductive tract infection, many of those who attended had gynecological problems other than STDs. Consequently, it appears that the camps would be more successful if the implementers were prepared to offer more services than STD detection and treatment alone.[47]

- In family planning clinics in Mexico, self-risk assessment rather than risk assessment by clinical staff prior to IUD insertions is being piloted to identify potentially infected women.[48]

Table 1

PREVALENCE OF STD AMONG WOMEN ATTENDING FAMILY PLANNING SERVICES

	GC	CT	TV	Syphilis	HIV
Dar es Salaam, Tanzania [51]	4.2	-	14.3	2.5	11.5
Nairobi, Kenya [52]	3.2	-	5.2	1.9	4.9
Maseru, Lesotho [53]	3	13	17	4	-
Martinique [54]	1	16.4	2.4	-	0

(GC: gonococcal infection; CT: chlamydial infection; TV: Trichomoniasis infection)

AN APPROACH TO STDS IN WOMEN: INTEGRATION OF STD SERVICES INTO BROADER REPRODUCTIVE HEALTH SERVICES

There has been growing interest in integrating STD care into family planning services, as a way to make STD services more accessible to women.[49] The International Conference on Population and Development held in Cairo in 1994 stressed that family planning services should be expanded to encompass more comprehensive reproductive health services and that more attention should be given to the prevention and treatment of STD, including HIV.[50]

Integration of STD services into broader reproductive health services could enhance their acceptability and effectiveness. However, this approach is less likely to reach adolescents, single, sexually active women, including female sex workers, and women who have completed childbearing.

How common are STDs among typical FP populations? In developing countries, data on STD prevalence among FP clinics are still scarce. Available data from Africa *(see Table 1)* indicate that STD rates found among these women reflect fairly well STD rates among general population low-risk women. The data show wide ranges of prevalences depending on the specific infection and on geographic origin. In countries where FP services have been restricted to married women who have completed their child-bearing, STD rates tend to be low. In places where "higher risk" women (such as adolescents or young single women) use FP services, STD rates are found to be much higher.

There are additional reasons for integrating STD/HIV into FP services. Women need to know if they are at risk for STD/HIV and, ideally, if they have an STD, to tailor contraceptive options and safer sex counseling to their needs. Considering that the most

Table 2

EFFICACY OF VARIOUS METHODS OF CONTRACEPTION AND STD PREVENTION [49]

Barrier methods Male condom	Protects against STDs, including HIV.	85-95
Female condom	May protect against STDs; method under study.	75-82
Spermicide (Nonoxynol-9 [N-9])	Protects against bacterial STDs; effect on HIV under study; effect on other viral STDs unknown.	70-85
Diaphragm with spermicide (N-9)	Protects against bacterial STDs; effect on HIV and other viral STDs unknown.	80-95
Cervical cap with spermicide (N-9)	May protect against bacterial STDs, but not studied; effect on HIV and other viral STDs unknown.	75-90
Hormonal methods Oral contraceptives	No protection against lower genital tract infection. Protects against symptomatic pelvic inflammatory disease (PID); may increase risk of cervical chlamydial infection; effect on HIV under study.	97
Implant (Norplant)	No protection; added risk unknown.	>99
Injection (DMPA, NET-EN)	No protection; added risk unknown.	>99
Other methods IUD	No protection; increase of PID risk in first month after insertion.	>97
Surgical sterilization (vasectomy and tubal ligation)	No protection against lower genital tract infections; tubal ligation may reduce risk of PID.	>99

effective methods for STD protection are less effective in preventing pregnancy *(see Table 2)*, the question arises whether health care providers should recommend that people use two methods. It is a complex and continually debated issue for family planning providers.

The answer remains unclear, especially now that data from the U.S. suggest that compliance with a barrier method (condom) decreases with the effectiveness of the contraceptive method used (such as oral contraceptives). The studies show that women who used oral contraceptives or were sterilized were less likely to insist on condom use than women who used a less effective contraceptive method or none at all. In Baltimore, Maryland, in the United States when sexually active teenagers were offered condoms to use in conjunction with oral contraceptives, only 4 percent used both methods simultaneously and consistently.[55] Until more data are available, the choice of promoting a dual method (condom and other contraceptive) versus one method for dual purpose (condom for both STD/HIV and pregnancy prevention) should be weighed by factors such as the "risk of unwanted pregnancy" and the "risk of HIV/AIDS" in each clinic setting. It is clear that in most developing countries both risks are high, taking into account the unavailability of safe medical pregnancy termination services and the high prevalence rates of STD/HIV in the general population.

In India, condoms have been promoted as a dual purpose method to try to motivate more consistent use among high-risk men. Through radio, peer educators, posters and brochures, truck drivers received reinforcing messages that condoms provide double protection. Condom sales at three outreach centers increased from ten per week prior to the intervention, to roughly 1,000 per week after 18 months.[56]

Table 3.
ADVANTAGES AND DISADVANTAGES OF DIFFERENT APPROACHES TO STD MANAGEMENT IN FAMILY PLANNING CLINICS [49]

Each FP provider manages STDs.	One stop for client.	Additional STD training for all FP providers. Additional management burden.
Refer to designated STD provider in FP clinic.	STD training necessary for only a few. Outcome of referral known. Quality of services known.	STD care dependent on few personnel. Additional management burden.
Refer to designated STD provider in other site.	Clinic services coordinated.	Outcome of referral unknown. Quality of services not ensured.
Refer to STD care elsewhere.	Easy.	Outcome of referral unknown. Quality of services not known.

More research also is needed on the patterns of dual method use. If an individual uses one method with a monogamous partner and adds condoms with other partners, this might effectively reduce risk, even if dual method use is not consistent in all encounters.

The diagnosis and treatment of STDs for women at FP services are the same as anywhere else and have been covered extensively in Chapter 8. Some issues specific to FP services are discussed here. When a woman presents with an acute **symptomatic STD** or admits having STD symptoms, the FP provider should apply the syndromic approach as discussed in Chapter 8. Whether all FP providers in one clinic should be trained in syndromic diagnosis of STD, or one provider per center should be trained (to whom all the women will then be referred) is still unclear. As summarized in Table 3, both strategies have advantages and disadvantages.

As in other settings, the main obstacle in STD management for women attending FP clinics is defining valid, feasible and affordable **case finding strategies,** especially for gonococcal and chlamydial cervicitis. So far, few attempts have been made to define risk profiling of STDs among FP attenders in developing countries. In a study in a rural FP clinic in South Africa, the presence of gonococcal and chlamydial cervicitis was associated only with young age and reporting more than one sexual partner. Algorithms including risk scores derived from this data did not have a high enough sensitivity and specificity to be acceptable for widespread use.

As pointed out in Chapter 9, the main reason why appropriate case finding strategies for gonococcal and chlamydial infections cannot be defined is the absence of a simple, rapid, affordable and valid test. Until such a test is available, imperfect approaches such as flowcharts that include risk profiling may still be a better option than doing nothing at all.

The concept of integrating STD services into FP services is still fairly new, and the many implications and consequences of this integration are still unclear. These may become clearer as actual programs are implemented.

APPROACHES TO THE SPECIFIC PROBLEM OF SELF MEDICATION

Two approaches to addressing the issue of self-medication have been field-tested in demonstration projects. One approach is to train pharmacy workers in syndrome management. The other approach is to promote syndrome-selective packages containing effective drugs and prevention materials. Both concepts are described in more detail below.

PHARMACY TRAINING

This approach is particularly relevant in settings where the health infrastructure is weak and where drugstore personnel are often the only recourse for medical advice and treatment.

Enlisting pharmacy workers in STD management acknowledges the significant, though informal role this sector plays in providing STD treatment. It also recognizes the sector's potential role in patient education (prevention education, compliance with treatment and partner referral), and condom promotion and distribution. However, it does not overcome the problem of patients purchasing partial prescriptions due to lack of funds. Moreover, it is often difficult in a public business setting to guarantee confidentiality and the privacy necessary for gaining customer trust.

Public health authorities and members of the medical profession usually have no objection to enlisting drugstore personnel in patient education. However, there is much less acceptance for explicitly training them in STD syndrome management. This is perceived by some authorities as condoning the dispensing of antibiotics without prescription, and seen by many in the medical community as a threat to their profession. For this approach to succeed, advocacy must be built among these groups and they must be engaged as partners in the intervention from the outset.

- In Nepal, drugstore personnel are being taught to dispense antibiotics using the syndrome management approach and to provide clients with preventive education and condoms. The intervention is being developed and implemented by the Nepal Chemists and Druggists Association in close collaboration with the Nepal Medical Association, the Department of Drug Administration and other relevant government agencies and university experts. The intervention also includes establishing appropriate referral networks between drugstores and clinics.[11]
- In Thailand, the pharmacists' association has adapted the syndrome management flipchart to train Bangkok pharmacists in STD management. It was developed for general practitioners by the Thai Medical Association for the Study of STDs.[11]

The impact of these interventions awaits evaluation. Over the long term, it is anticipated that as services improve in the formal sector, there will be a gradual shift in health-care-seeking behavior to facilities that offer privacy and are conducive to a more thorough clinical assessment.

MARKETING PREPACKAGED THERAPY

Prepackaging of antibiotics for urethritis along with prevention materials (condoms, partner referral cards, instructions and educational material) was field-tested in Cameroon as a demonstration project to raise the level of effective treatment. The project was started to address the following identified problems based on research cited above[6] indicating:

- High incidence of urethritis in young men
- High levels of self-treatment
- Widespread use of inappropriate and ineffective drugs by physicians and pharmacies
- Widespread under-medication due to partial prescription filling.

A kit for urethritis was developed under the brand name *Mstop,* the French abbreviation for STD (MST) and the word STOP. The kit contained two 500 mg tablets of cefuroxime axetil as a single-dose therapy for gonorrhea; twenty 100 mg tablets of doxycycline for a 10-day course for chlamydial infection; an STD education leaflet; eight condoms; and two partner referral cards encouraging partners to seek medical care. The kit was priced at US $17 with the brand-name antibiotics accounting for most of the cost. At the time of the project, generic, untaxed drugs could not be sold in Cameroon. This price was found to be competitive when compared to the mean cost per STD episode

estimated in a pharmacy exit survey.[6] Although the kit was originally designed to be sold in pharmacies without prescription, health authorities ultimately only allowed *Mstop* to be sold in a limited number of government clinics and private pharmacies.

The sales never achieved their target. This was due, in part, to poor physician acceptance of syndrome management, since a consensus on the syndrome approach to STD management had not been reached in Cameroon when the project was implemented. It was also due to the limited distribution of the product. However, follow-up with patients who received the kit showed a high level of satisfaction: 98 percent reported taking the two tablets of cefuroxime axetil and 83 percent reported completing the 10-day course of doxycycline; 84 percent reported using condoms while on treatment; and 44 percent used their partner referral cards. The number of partners who actually sought treatment could not be monitored.

Based on the Cameroon project, the following recommendations should be considered in implementing future projects using the syndrome selective packaging approach:

- The medical community's and the Ministry of Health's endorsements of the syndrome management approach to STDs should be a prerequisite since syndrome selective packaging implies acceptance of this approach.
- The project should be launched as an integral part of the national STD control program and the antibiotics chosen for the kits ideally should be based on national STD treatment guidelines and drug recommendations. This also ensures that the drugs selected for the kit are approved by the country's regulatory bodies. Ideally, these national guidelines should be based on laboratory and epidemiologic data.
- Local pharmaceutical regulations need to be clearly understood and the influence and power of the pharmaceutical industry cannot be underestimated. For example, generic drugs, which would make the kits more affordable, are not allowed to be sold in some countries. In some, brand-name drugs cannot be promoted or advertised. In others, drugs that are sold are subject to import taxation.
- A project advisory committee should be formed and consulted throughout the project, from the design phase through the implementation phase. The committee should include experts and key influential representatives of the Ministry of Health and other relevant government authorities and regulatory bodies, the medical, pharmacy, and research communities, and the pharmaceutical industry.

Although the Cameroon project did not achieve the anticipated level of success, the rationale for marketing syndrome selective kits for treatment and prevention remains valid. The final word on this approach should be reserved for after it has been given a fair chance to succeed. The concept of packaging effective drugs (ideally single-dose drugs) and prevention material for managing STD syndromes could be modified for specific country situations. Here are some examples:

- A syndrome package of generic drugs and prevention materials could be sold in public sector clinics as part of a cost-recovery scheme. By limiting sales to the public sector clinics where drugs are often supplied free of charge or for a nominal cost, there might be less resistance from the pharmaceutical industry.
- A syndrome management kit of effective drugs and prevention materials could be marketed to health-care providers through the usual and accepted routes of current pharmaceutical marketing. This would ensure consistently effective treatment for STD syndromes and reinforce the syndrome management approach.
- A syndrome management kit could be marketed to pharmacists to be made available by prescription.
- A syndrome management kit could be marketed to the public as an over-the-counter product available without prescription. The argument that this approach will increase antibiotic resistance in a community would be attenuated if single-dose, single-pill antibiotics were provided in the kit.

CONCLUSION

In contrast to the enormity of the STD problem, the existing STD service infrastructure, whether it be a vertical or horizontal system, is either weak or nonexistent in most developing countries. Building this infrastructure is essential for long-term STD control, but will take time. In addition, a broader approach to service delivery must be envisioned that engages primary health-care, MCH and FP services; enlists the private and informal sectors as partners in service delivery; provides services that are convenient, effective, expedient and non-stigmatizing; and, recognizes the critical role of preventing infections, in addition to treating infections. In the meantime, concomitant interventions are needed that can be implemented right away and can achieve a rapid reduction of STDs, making use of existing and often scarce resources and infrastructures.

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CHAPTER 14

STD Program Monitoring and Evaluation

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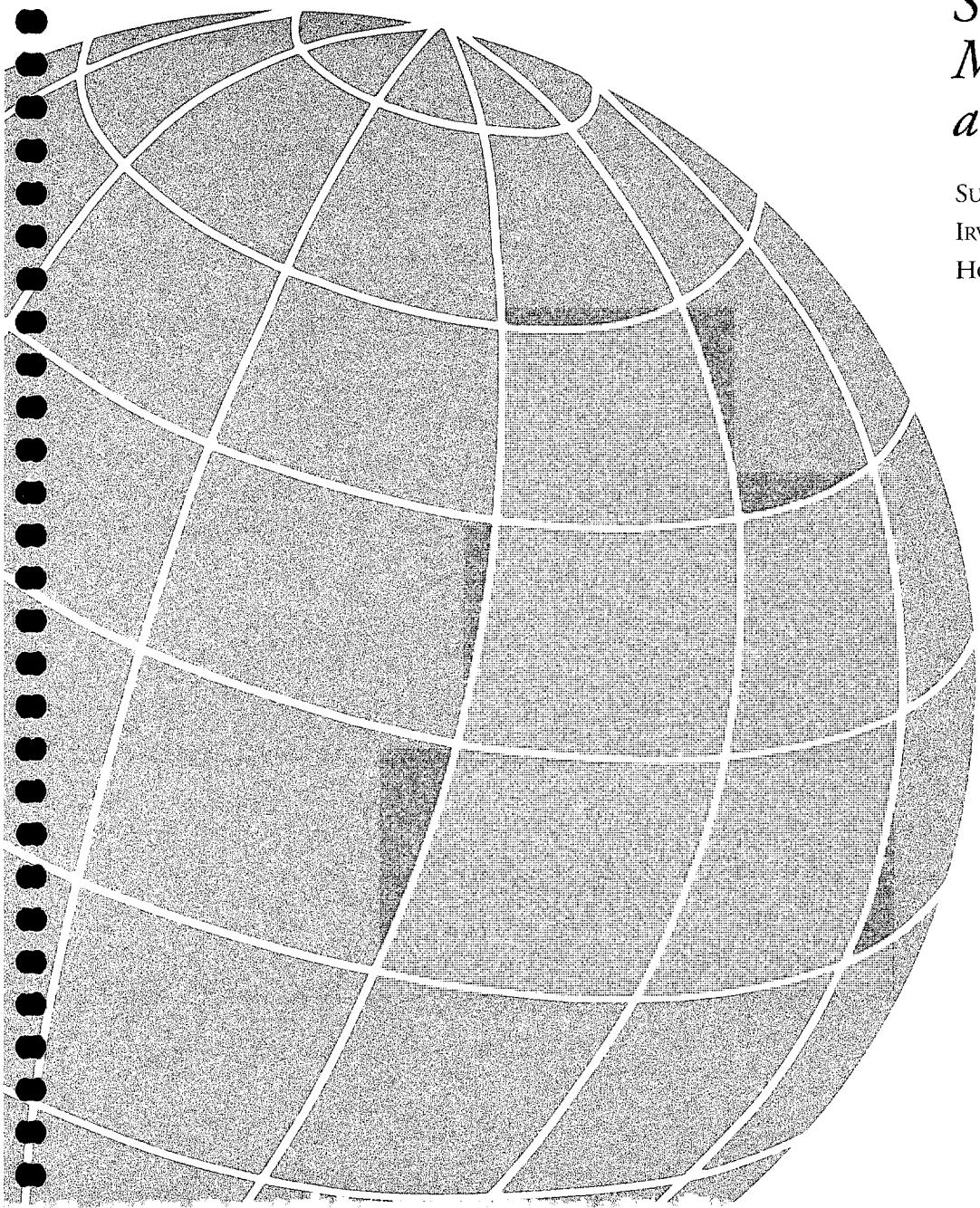


preview CHAPTER 14

STD Program Monitoring and Evaluation

INTRODUCTION

This chapter discusses the role monitoring and evaluation plays in STD/HIV control. The monitoring phase tracks and counts events, activities, people and objects. It includes either periodic or continuous data collection.

Evaluation documents the magnitude of STDs, including HIV, and the positive impact of control measures, information that can be used to convince policy makers groups of the value of control programs.

SETTING GOALS AND OBJECTIVES

Defining goals and objectives is the first step in monitoring and evaluating an STD control program. A goal refers to the long-range program activity, while an objective is usually a statement of shorter-term accomplishments.

DATA COLLECTION AND ANALYSIS: MONITORING

The monitoring and evaluation process should measure parameters that describe what an STD control program is actually doing. These include measures to assess service delivery, staff performance, adequacy of staffing patterns, client satisfaction and response, and resource needs and allocation.

SERVICE DELIVERY

Examples of monitoring parameters for service delivery include the number of patient visits (per day, week, month); number of condoms distributed; and the number of cases of specific syndromes seen.

STAFF PERFORMANCE

Monitoring staff and personnel-related factors involves the following components:

- Determining whether the staff-to-patient ratio is appropriate to the patient load
- Ensuring that staff receive both initial and ongoing in-service training
- Ensuring that staff receive supervision and feedback

Client Satisfaction and Response

A complete record system and routine reports give staff and managers information on the number of patients using STD services; the types of patients (sex, age group, etc.) coming in; the number of initial patient visits compared with the number of repeat visits; and the proportion of patients using the facility as their first treatment option.

Resource Needs and Allocation

Routine monitoring of costs allows an STD program to pace itself, stay within budget, and assess efficiency and cost-effectiveness.

DATA COLLECTION AND ANALYSIS FOR EVALUATING PROGRAMS

A periodic evaluation can focus on one particular objective at a time or attempt to assess progress toward all objectives and goals. The most common methods of data collection for evaluating the biological effectiveness of STD control programs are the following:

- Surveillance data from the STD control program
- STD-related morbidity indicators collected from non-STD service sites
- Results of special studies conducted either by the STD control program itself or by others

Case Study Examples

Two examples from Thailand and Rwanda show how relatively few pieces of information can be combined to help programs begin to understand their impact on STD transmission. A simple question-evaluation process can give some highly useful answers.

USE OF INFORMATION AND DATA

Focusing clearly and at an early stage on how data will be used helps a program in a number of ways. For example, it helps it avoid collecting irrelevant data, sustain the flow of information and ensure that findings are used to improve the STD program as it evolves.

CONCLUSION

As an integral part of an STD control program, a successful monitoring and evaluation system is used as a basis for documenting a program's value and for programmatic improvement.

INTRODUCTION

Monitoring and evaluation are critical to the success of any STD control program. The monitoring phase tracks and counts events, activities, people and objects and can consist of either periodic or continuous data collection. The information gathered in this process, such as new trends and strengths and weaknesses of the program, should be used to improve programs.

The evaluation phase periodically measures and analyzes progress toward attainment of stated goals and objectives. This analysis may be based on existing monitoring data that is aggregated or otherwise manipulated, or on a separate, unique data collection system. In addition, by documenting the magnitude of STDs (including HIV) and their consequences, and by showing the positive impact of control measures, evaluation can help program managers convince governments and funding agencies that STD/HIV control programs are a cost-effective use of scarce resources.

The purpose of monitoring and evaluation is to ensure appropriate and high-quality services. Therefore, monitoring and evaluation should be an integral part of the design, development and implementation of STD control programs, not just a periodic activity linked to broader planning or funding cycles. The more integrated the evaluation system, the more successful it will be, and the less likely practitioners will lose interest in it or find it unduly burdensome.

Interpreting evaluation data must always be done cautiously. Biases may be inherent in the data collected, the methods used for its collection and the sites included in the data collection process. A common example of

bias is found in evaluating reported cases of STDs, where the patient population, type of STDs and number of patients seen may differ widely between the private sector and public clinics, which usually are the source of most case reports. Because cases are often grossly under reported by private clinicians, the overall number of patients seeking care for STDs in the private sector may be underestimated. As a result of such biased information, important service areas may be left out of either an STD control program or its monitoring and evaluation system.

SETTING GOALS AND OBJECTIVES

The first step in monitoring and evaluating STD control programs is to define the goals and objectives of the program. A goal can be defined as the long-range purpose for all program activity, while an objective is usually statement of intermediate (shorter-term) and more specific accomplishment. For example, the goal of an STD control program may be "To reduce the morbidity and mortality from STDs in population X" or "To reduce the incidence of genital ulcer diseases by 25 percent within five years." Many factors will contribute to a goal, and a number of different objectives will need to be defined in support of it. The long-range goal of the program should be stated explicitly to help individuals at all levels of the program understand the ultimate rationale for their activities and how the intermediate objectives contribute to the realization of those goals.

The objectives in an STD program should reflect both operational and biomedical efforts or activities. For example, an operational objective might relate to increasing the number of STD patients evaluated, treated and counseled about STD and HIV risk-reduction behavior in a given time period. A biomedical objective might be increasing the percentage of patients given the correct treatment regimen for urethral discharge and then cured of the infection.

Goals and objectives must be meaningful and realistic. Otherwise, program staff and managers will become discouraged. STD prevention and control programs at different stages of development or experience should have different goals and objectives specifically tailored to their situation and resources. Shorter-term objectives allow progress to be recognized and celebrated and can be useful in motivating personnel at all levels to continue improving their performance. Periodic reviews of all goals and objectives should be scheduled to ensure their continued feasibility and relevance to the overall program and to the ever-changing environment in which STD control programs operate.

Furthermore, program goals and objectives should be set collaboratively by all parties involved and should not be imposed by outside evaluators. Encouraging input from STD program staff at many levels will increase compliance with data collection plans. It will also help ensure that the data selected to measure progress toward a given goal or objective fit the capabilities of the facility. For example, service sites with no laboratory services may file monthly reports of syndrome-based diagnoses, treatments used and patient demographics rather than reports based on laboratory results.

Potential interpretation problems should be considered when objectives and goals are set so that biases can be anticipated. The presence of bias does not invalidate a measure if the amount of error can be estimated. For example, laboratory reporting of positive rapid plasma reagins (RPRs) is a very accurate, mechanism to estimate syphilis prevalence. But the reports may represent old, new and even treated cases of syphilis. New cases would be very difficult to distinguish from the others. However, over the long term, trends in new or incident cases of syphilis can be estimated by measuring syphilis prevalence in new, sexually active individuals (persons under the age of 20, for example) or by the proportion of specimens that demonstrate RPR titers greater than 1:8.

The process of setting goals and objectives can be greatly facilitated by a comprehensive baseline assessment of the physical and human resources and actual services available at the various STD control program facilities. Examples of parameters to assess include the following:

- Whether prevention information is part of the patient/provider interaction
- What types of patients currently utilize the STD services (sex, age, marital status, etc.)
- Existing logistical and managerial support systems
- The nature and scope of the existing data collection mechanisms

Simple features such as the average patient waiting time, number of patients per day, number and type of staff at the facility at all times, availability of antibiotics and condoms, and adequacy of water, lighting and cleanliness also are essential to providing good services and should not be overlooked.

This type of baseline assessment will help program managers identify critical areas in need of improvement, help determine priorities and set realistic objectives and goals for an STD control program. For example, if a particular facility identifies chronic shortages of drugs and condoms or insufficient examination space for the current patient load, the program's first objective could be correcting these problems.

Finally, determining what information will be most useful and affordable to collect is key to the sustainability of monitoring and evaluation efforts. The quality and quantity of the data, together with the cost and feasibility of obtaining the data, should be weighed when planning the STD control program's monitoring and evaluation activities. It may be more important, particularly in the early phases of program upgrading, to focus on a small number of easily collected pieces of data rather than on trying to implement a complex system of sophisticated measures that may collapse under the weight of reporting requirements. A good rule of thumb is to collect only what is needed and to use what is collected.

DATA COLLECTION AND ANALYSIS: MONITORING

The monitoring and evaluation process should measure parameters that describe what an STD control program is actually doing. These include measures to assess service delivery, staff performance, adequacy of staffing patterns, client satisfaction and response, and resource needs and allocation. Current clinic records can and should provide useful parameters and are one of the best places to start defining data collection options.

SERVICE DELIVERY

Some examples of monitoring parameters for service delivery include the following: the number of patient visits (per day, week, month); the number of condoms distributed; and the number of cases of specific syndromes seen (e.g., urethral discharge, genital ulcer or vaginal discharge). Such information can come from any service delivery source: public STD clinics, primary-care facilities, private-sector health-care providers or hospitals.

Surveillance systems and the reporting of specific diseases or syndromes is a special type of monitoring that can often include laboratory facilities as a data source (for syphilis serology, for example) and is addressed at length in Chapter 15 of this manual.

How might some of the examples above be useful to an STD control program?

The number of people who seek treatment for STDs and the number of cases of a specific syndrome diagnosed during a specified time period (e.g., a month), including breakdowns by sex, age and ethnic group, (if applicable), can help managers begin to understand the scope of the STD problem in a particular area. This is particularly true if such data are collected over time. Such information can also help managers anticipate changing personnel and supply needs.

The number of condoms distributed or sold through service delivery systems during a specific time period will inform logistics and supply systems if their services are adequate, as well as track, in general terms, the effectiveness of basic prevention efforts.

Two more complex pieces of information that can and should be collected as part of periodic monitoring are directly related to the quality of the care provided. They are "Prevention Indicators" (PIs) numbers 6 and 7 of the World Health Organization/Global Programme on AIDS (WHO/GPA).[1,2] These indicators measure the following:

PI 6: The proportion of clients presenting for STD diagnosis and treatment who are treated according to national guidelines.

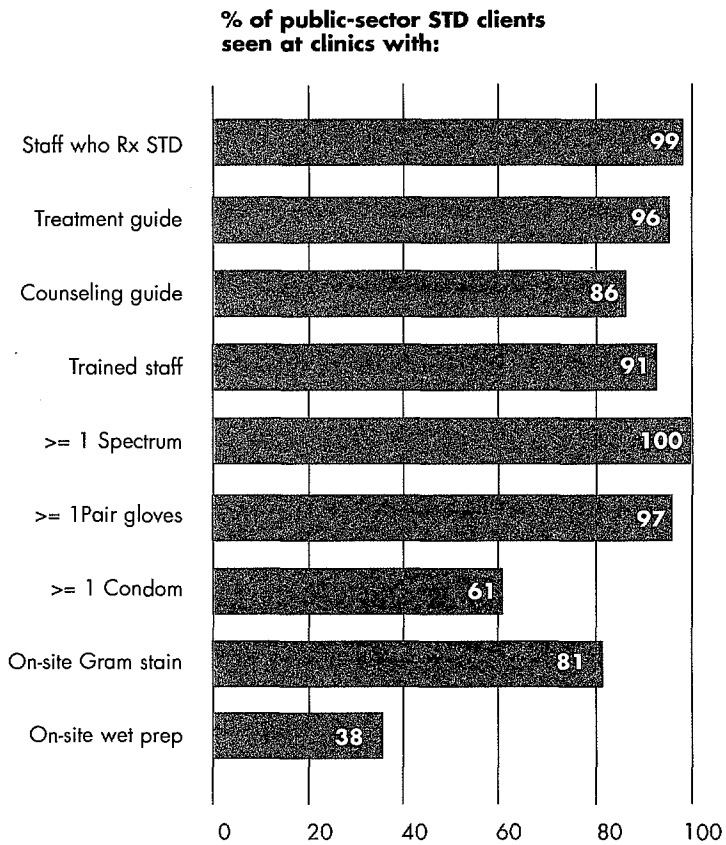
Obtaining this information requires a combination of some of the routine data collection described above and direct observation to assess the correct use of the treatment protocol.

PI 7: The proportion of clients presenting for STD diagnosis and treatment who receive appropriate prevention-related services.

Special data collection (observation of the provider) is also required to obtain this information.

Figure 1

STD CLIENTS SEEN IN PUBLIC-SECTOR CLINICS WITH NEEDED STAFF, TREATMENT GUIDELINES, AND SUPPLIES, WEIGHTED BY TYPE OF CLINIC, JAMAICA, 1991



It has proven difficult in some settings to strictly adhere to the GPA protocol. Provider and client interviews have sometimes been used in lieu of the observation component. While the use of interviews alters the validity and comparability of the data relative to the GPA protocol and may introduce additional bias, it may be the only option possible, particularly when dealing with private practitioners. Nonetheless, if practitioners use interviewing as the alternate technique of choice, comparisons can be made within a country, region or program.

The following figures show results from two facility-based assessments conducted in Jamaica in 1991[3] and in Malawi in 1994[4]. The Jamaica data were collected as part of early testing of the GPA protocols and will serve as the baseline for subsequent program improvements and evaluation.

Figure 2

History-taking and examination of STD clients in public-sector clinics, weighted by type of clinic, Jamaica, 1991

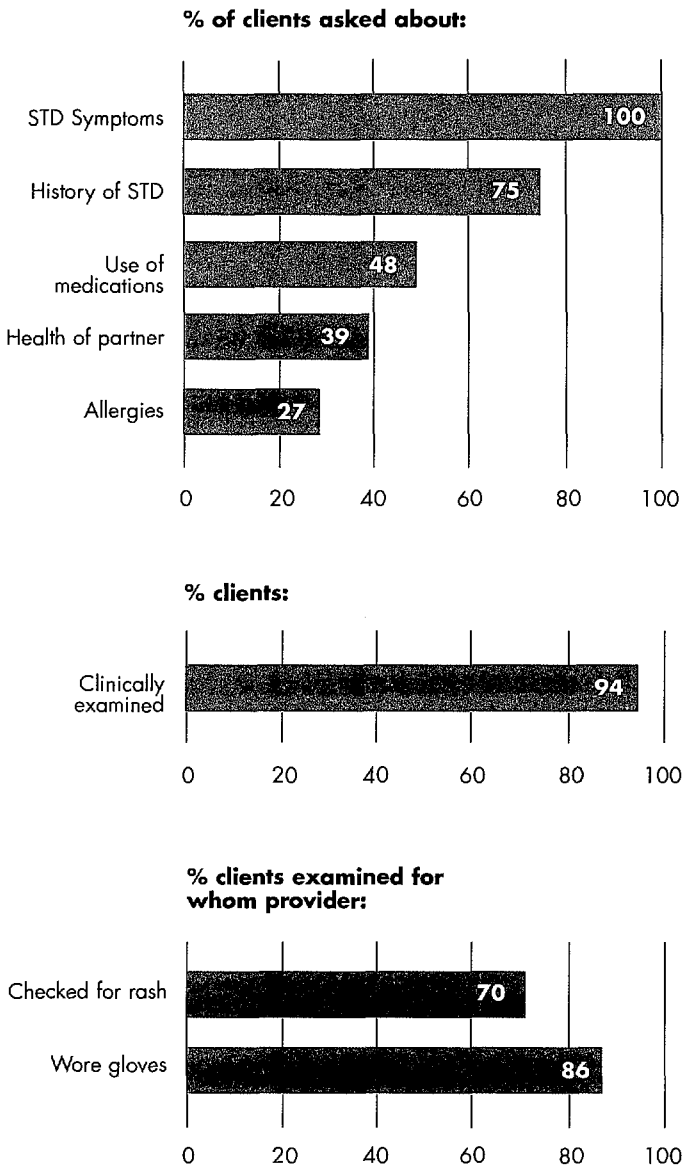
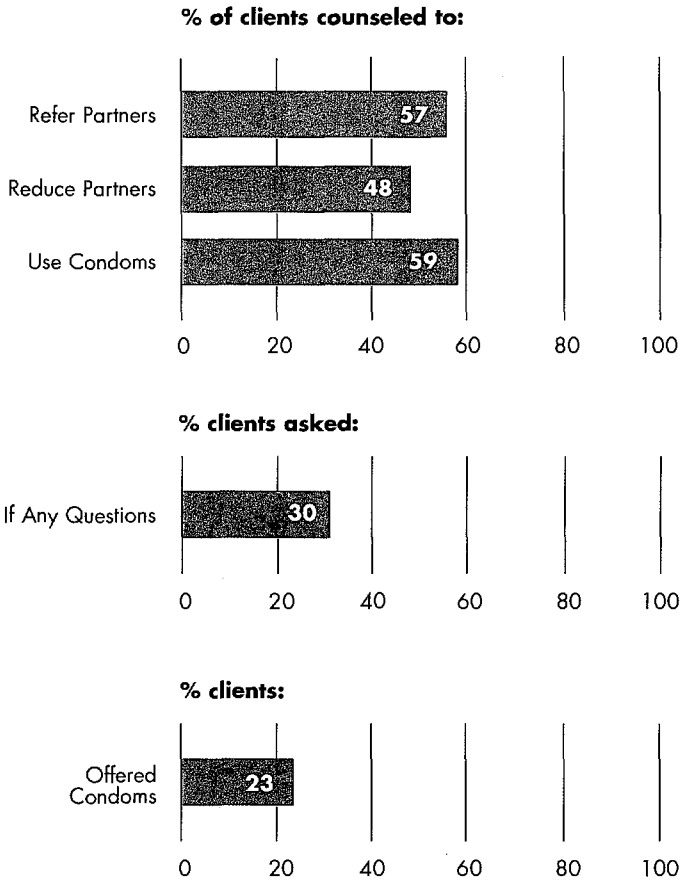


Figure 3

STD client education and condom distribution in public-sector clinics, weighted by type of clinic, Jamaica, 1991



The Malawi data were specifically collected as baseline information for planned upgrading of selected sites within the STD service-delivery system. The "pilot and non-pilot" sub-groups in two of the graphs define whether the facility was participating in a National AIDS Control Programme (NACP)-implemented STD service upgrading process.

The data collected in this assessment process provide very practical guidelines for programs, defining in a detailed manner the strengths and weaknesses of the facilities and personnel within the service-delivery system. The parameters that are lowest may be targeted by a program for special and intensive correction through procurement of supplies and commodities or staff education and training.

Staff Performance

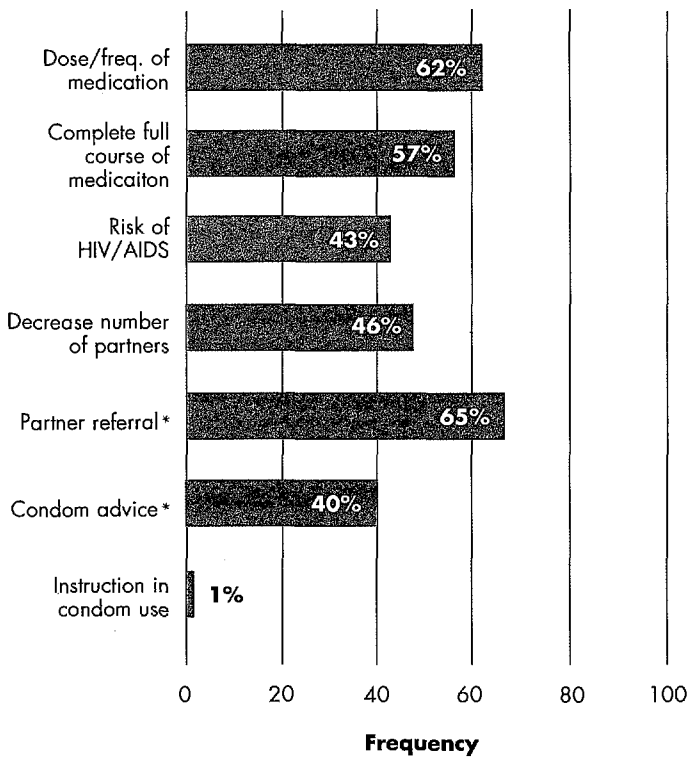
Monitoring staff and personnel-related factors includes observation and analysis of a number of components:

- Determining whether the number and utilization of staff is appropriate to the patient load (e.g., time spent per patient)
- Ensuring that adequate initial training and appropriate refresher or in-service training is provided to all staff members not only as a means of assessing their skills and informing them of new protocols but also as a way to update staff on progress toward program objectives and goals
- Ensuring that appropriate on-site and external supervision and feedback is provided to all staff

Supervisors should structure training efforts based on the information obtained from periodic assessments of personnel performance and facility capabilities *(see Chapter 6).*

Figure 4

Provider performance on aspects of patient education during observed encounters, Malawi, 1994.



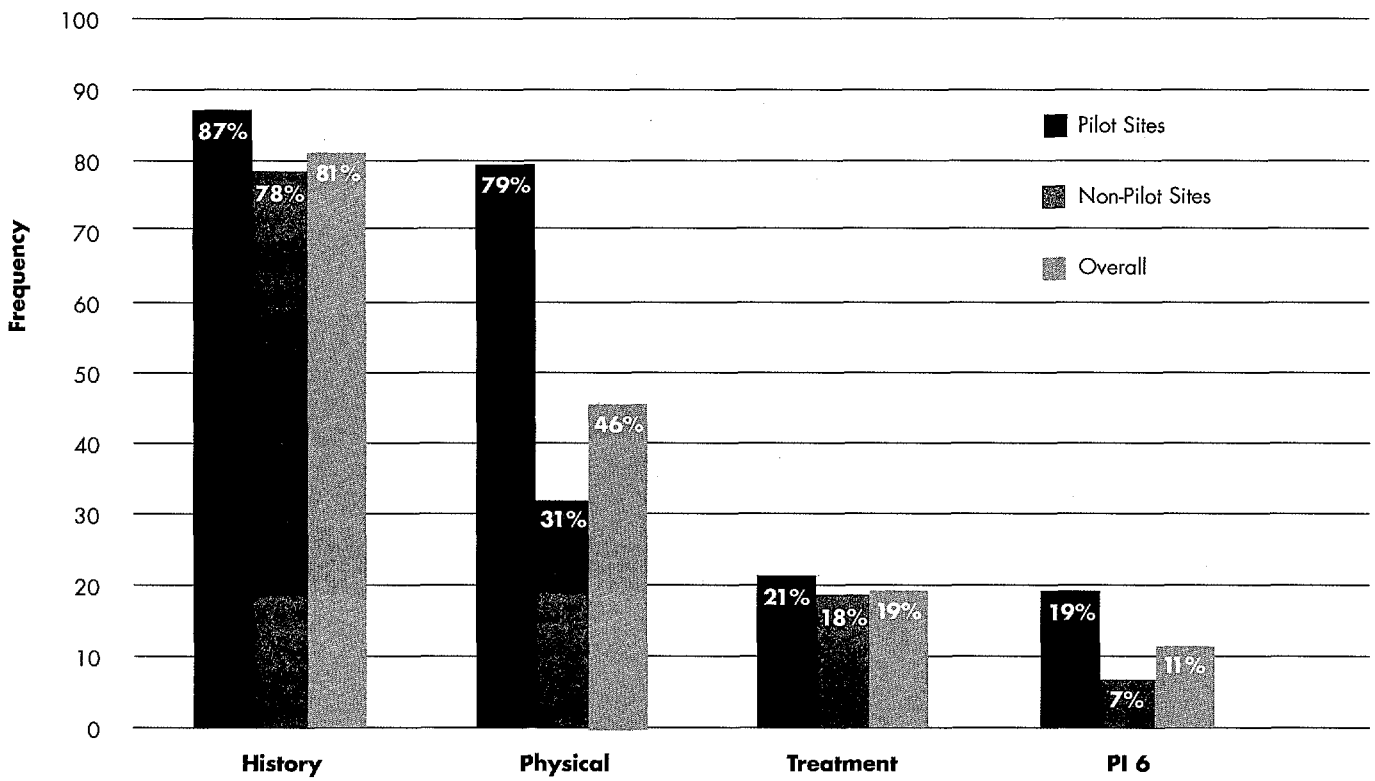
** Indicates elements included in the assessment of P17.*

Client Satisfaction and Response

In any health-delivery system, the staff is only half the picture. The other half is the client, or patient, population. Monitoring of patients relies most heavily on a complete, clear patient record system and simple, routine reports. These reports will give program staff and managers the following, pertinent information:

- The number of patients using STD services and, when the STD services are part of a primary health care or comprehensive clinic, what proportion of the patient load is attributable to STDs.
- The types of patients using STD services. Does one sex or age group predominate? Are particular sub-populations present in the patient base? For example, do members of the uniformed services use the clinic services? To what degree?
- The proportion of patients making initial clinic visits compared with repeat or return visits. This information can help program managers qualitatively assess the effectiveness of treatment and prevention counseling.
- The proportion of clients seeking treatment at the facility as a first option, either independently or by referral. This parameter can assist program managers in assessing treatment-seeking behaviors, partner notification and other referral efforts.

Figure 5
Components of PI 6: STD pilot sites, non-pilot sites, and overall, Malawi, 1994.



Resource Needs and Allocation

There are never enough financial resources to implement the perfect program. Routine monitoring of operating costs, such as salaries, travel expenses, and supplies and drugs, as well as new capital costs, such as remodeling and equipment purchases, is a very important part of program monitoring. Tracking these costs allows an STD program to pace itself, stay within budget, and assess efficiency and cost-effectiveness over time.

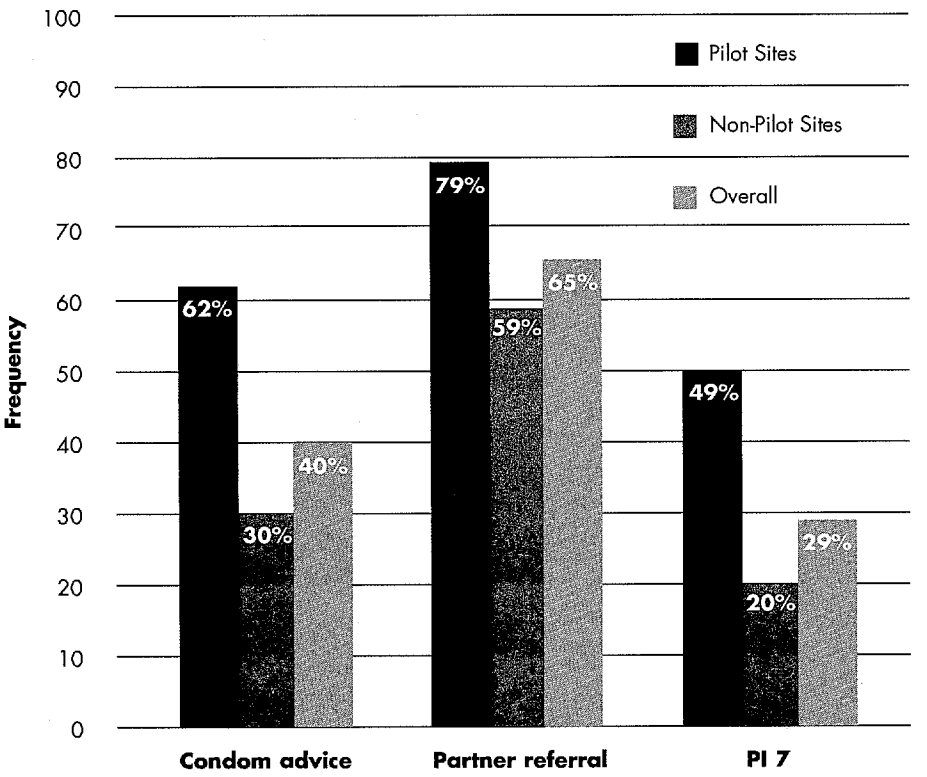
DATA COLLECTION AND ANALYSIS: EVALUATION

A periodic evaluation can focus on one particular objective at a time or attempt to assess overall progress toward all objectives and goals. The specific factors assessed for an evaluation are dependent upon the goals and objectives of the program.

For example, if a program's goal is to reduce the prevalence of urethral discharge or gonorrhea, the objectives leading to that goal would include an increase in condom distribution and partner referrals. The program evaluation would assess progress toward achieving those objectives over time and then compare those gains with the prevalence of urethral discharge or gonorrhea during the same time frame.

Figure 6

COMPONENTS OF PI 7: STD PILOT SITES, NON-PILOT SITES, AND OVERALL, MALAWI, 1994.



Understanding that many factors, both internal and external to the STD control program, affect the prevalence of any disease or condition is, of course, critical to the interpretation of evaluation findings. The most common methods of data collection for evaluating the biological effectiveness of STD control programs are the following:

- Surveillance data from the STD control program
- STD-related morbidity indicators collected from non-STD service sites
- Results of special studies conducted either by the internal STD control program or by an outside group

The advantages and disadvantages of each type of data collection will be described in the sections that follow.

STD Surveillance Systems

A surveillance system is a mechanism by which regular, standard reports of specified diseases, syndromes, pathogens or treatments are provided to a central authority for compilation and analysis. Chapter 15 provides detailed information on surveillance systems.

Non-STD Service-Dependent Data Sources

One of the most valuable sources of data for evaluating the success of an STD control program is derived from antenatal care services. In settings where use of antenatal services is high, serologic screening and treatment of antenatal patients for syphilis meet two important health objectives:

- It allows for treatment of syphilis in women and prevention of congenital syphilis *(see Chapter 9).*
- It provides the STD program with a relatively unbiased estimate of the prevalence of at least one STD in the sexually active population *(see Chapter 15).*

Reporting of certain other diseases or conditions, including cases of congenital syphilis, gonococcal ophthalmia neonatorum and pelvic inflammatory disease (PID), may also be particularly useful for the evaluation of STD control efforts. The prevalence of these serious sequelae of STDs helps define the spread of STDs in the population. However, the diagnosis of these conditions is often difficult and costly and should not be undertaken lightly.

Special Studies

Special studies are used to answer certain questions or test a specific hypothesis. They are particularly useful for evaluation when they confirm information collected in a less controlled manner or provide information that will aid in the interpretation of routinely collected data. These studies are designed and implemented to answer specific questions in one or more designated sites following a standardized protocol over a set period of time.

Examples of such special studies include surveys of patients, or the broader population as in the periodic national Demographic Health Surveys (DHS), on risk behaviors or use of or satisfaction with services, assessments of treatment compliance or partner referral, and laboratory studies to ascertain resistance patterns of prevalent STDs *(see Chapter 12).*

Because so many factors can affect STD transmission and the reported data, the evaluation process should try to combine several different sources and types of data. By using a variety of methods and data, the evaluation process will provide a balanced, less biased measure of STD control program effectiveness. For example, a program should compare data on the prevalence of syphilis from both clinic records and surveillance or special serostudies instead of just relying on one source.

Case Study Examples

Two examples from Thailand and Rwanda show how relatively few pieces of information can be combined to help programs begin to understand the effect they are having on STD transmission. In Thailand, where prevention activities have focused on increasing condom use and access to STD treatment by commercial sex workers (CSWs), cases of STD in males in private sector clinics fell from over 237,000 in 1987 to approximately 38,800 in 1993. In this same time frame, reported condom use by CSWs rose from less than 20 percent of sex acts to 94 percent in June 1993, with a concomitant drop in new STD infections of 54 percent.[5]

A similar phenomenon has been reported in Rwanda by the NACP, where they examined rates of urethritis, as well as condom distribution, to military recruits.[6] While incidence of urethritis had been

approximately 10 percent in 1985 and 1986, once a condom promotion and distribution program began and reached a distribution level of approximately 5 condoms per month per recruit at the end of 1987, the incidence of urethritis dropped to approximately 2 percent.

While neither of these examples can directly attribute the observed changes in the incidence of STD to the interventions, the data are strongly suggestive of the effect that prevention activities can have upon rates of STD.

Furthermore, while all STD programs seek to reduce the rates of STD, the time frame, technology, personnel and geographic or population boundaries for control activities are specific to each situation. For example, an STD control program for the small island nation of Sri Lanka might have the same goal as a program in its large neighbor, India: "reducing the rate of syphilis to less than 2 percent nationwide." In each country, however, the programs would use vastly different strategies and methods to achieve this goal and evaluate their progress. Sri Lanka may be able to measure its progress through an active "universal" reporting system, where each case of syphilis in the entire country is counted. India, however, may rely on data collected only at selected sites or in populations serologically tested at regular intervals to determine success.

An example of a simple evaluation process for a single clinical setting would be one that answered the following questions:

1. How many cases of the various STDs were reported during this period?

2. How does that number compare to the cases reported during the last period as well as comparable periods in previous years?

3. Do the comparison reveal any trends? Are there specific factors that have caused this trend, such as changes in personnel, clinical hours, user fees, clinical definition or counseling techniques, or seasonal or social changes?

4. Are these syndrome or disease trends different when broken down by age, sex, social status, special group or geographic area?

5. If any of the STD diagnoses were confirmed in the laboratory, was the laboratory diagnosis consistent with the clinical diagnosis? Were there any significant laboratory trends, such as rates of resistant gonorrhea? Do these trends correlate with an increase in treatment failures?

USE OF INFORMATION AND DATA

Information feedback mechanisms should be established at the same time as monitoring and evaluation parameters and data collection methods are defined. Feedback mechanisms can be as simple as routine monthly communication from a supervisor or manager to the clinic staff about the most recent number of patients treated and the trends in STD at the facility, or as sophisticated as annual, formal reports on all aspects of program performance.

Focusing clearly and at an early stage on how data will be used helps a program in the following ways:

- By not collecting data that are of no direct benefit to the goals of the program
- By keeping information flowing in both directions
- By improving the quality of the data collected
- By ensuring that the findings of the monitoring and evaluation efforts are used to improve the program
- By demonstrating the progress and effectiveness of the program to improve internal morale and positively influence external audiences involved in funding and expansion

The following table categorizes examples of the data collection and evaluation tool options for STD control programs, including indications of relative difficulty and cost. This information is provided to assist program managers and others as they determine the type of data needed or desired and the fiscal and human resources available in a program for evaluation efforts.

Data Collection and Evaluation Tool Options

Commodities (e.g., condoms, drugs or educatianal materials)	High	Monthly	Low	Low
Laboratory data	Variable	Monthly	Low	Low
Financial	High	Monthly	Low	Low
Other data sources (DHS, etc.)	Variable, due to timing and content	Variable, not linked to STD program	Low (to STD program)	Low
Surveillance data (e.g., # of patients by syndrome)	High	Monthly	Low	Moderate
Supervisory visits and feedback at: 1) the facility level and 2) the individual level	High	Variable 1) 3 mos 2) 6 mos	Moderate to High	Moderate to High
Case management - PI 6 and 7	High	1-2 years	Moderate	Moderate to High
Periodic surveys of: 1) behavior and 2) STD etiologies	High	Variable 1) 2-4 yrs 2) 2-3 yrs	Variable 1) Mod/High 2) High	Variable 1) Mod/High 2) High

** The costs indicated in this column are for maintenance of an existing system. Initiating or significantly modifying systems can be quite expensive.*
 # The difficulty indicated is related to maintaining a system in a functional manner, not the startup of a system.

CONCLUSION

Monitoring and evaluation of an STD control program is a process used to ensure the quality and appropriateness of services. The first step is to define the goals and objectives of the program. Goals must be meaningful yet achievable. Getting input from many levels of the organization will increase compliance with data collection. Problems of interpretation and sources of bias should always be considered. A comprehensive baseline assessment may be helpful when setting goals and objectives.

Monitoring tracks, counts and measures what an STD control program is actually doing. It can be either periodic or continuous. Surveillance is an important component of monitoring. It is a mechanism by which regular, standard reports of specified diseases, syndromes or pathogens are provided to a central authority for analysis. Monitoring of financial resources is a very important part of monitoring activities.

An evaluation periodically measures and analyzes progress toward attainment of stated goals and objectives. It summarizes the monitoring information, interprets any developing trends and compares it to expectations. Feedback mechanisms can help ensure that information obtained from monitoring and evaluation is used to improve the program. As an integral part of an STD control program, a successful monitoring and evaluation system is used as a basis for programmatic improvement and to document a program's value.

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CHAPTER 15

Surveillance

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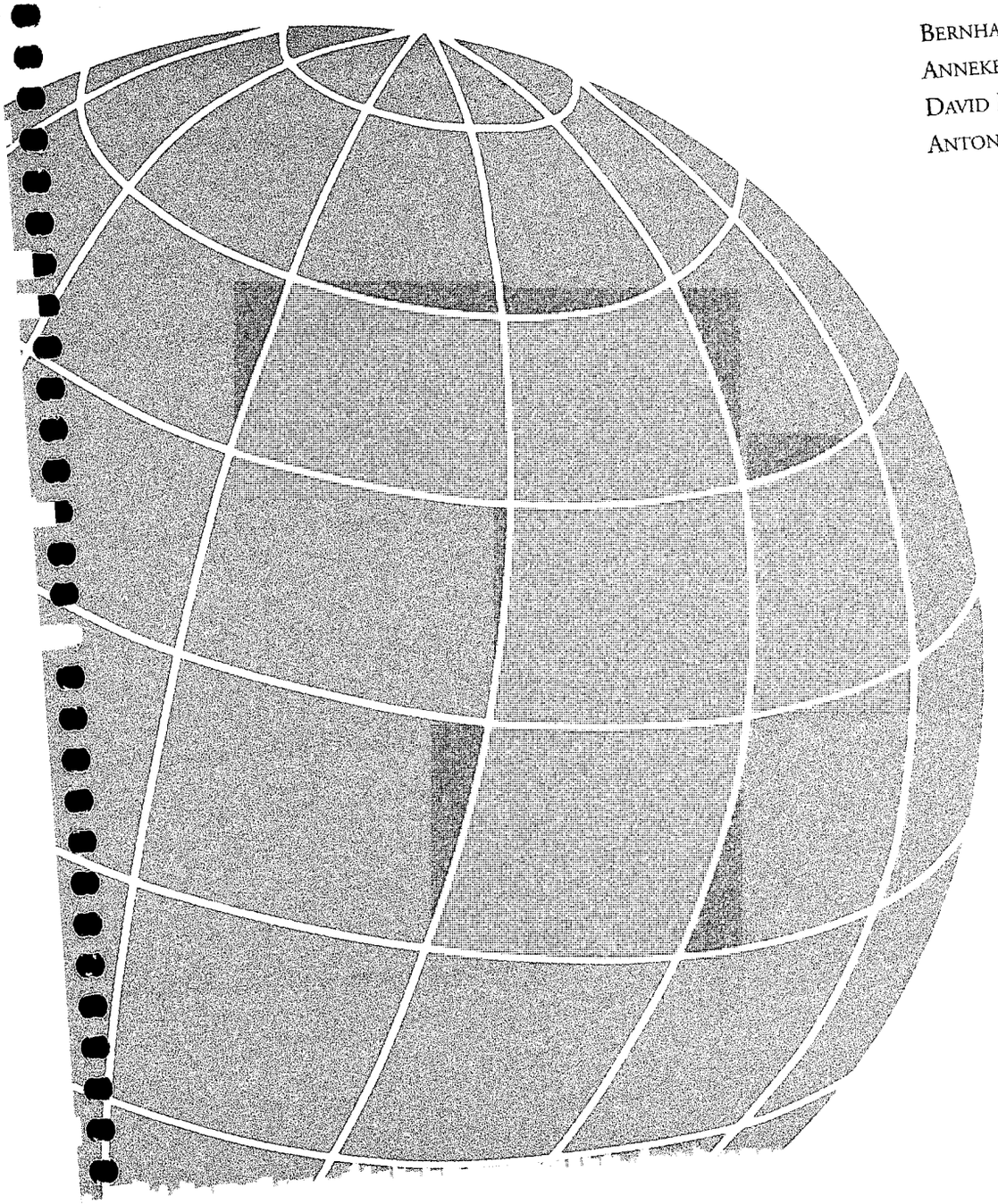


preview CHAPTER 15

Surveillance

INTRODUCTION

This chapter provides recommendations for developing an STD surveillance system, which collects basic information on the frequency and distribution of diseases as well as population patterns. This data is important when planning and monitoring an STD program.

OBJECTIVES OF STD SURVEILLANCE

The main objectives are the following:

- Estimate the STD problem's magnitude; define needed resources, raise awareness and gather support.
- Measure frequency, distribution and antimicrobial sensitivity; define and monitor procedures.
- Monitor trends, reinforce political support, monitor and improve the existing program.

TYPES OF SURVEILLANCE

In general, there are three types of disease surveillance:

- **Passive surveillance** can be useful in reporting STD sequelae, indicating health-care procedural failures, but does not provide information needed to plan and monitor programs; passive systems should be incorporated into more reliable and cost-effective surveillance systems.
- **Enhanced surveillance in sentinel sites and populations** involves cooperation and systematic data collection from a limited number of facilities, leading to higher quality and more consistent information.
- **Specific surveys** are the most cost-effective measure for determining prevalence of STDs in specific population subgroups, the distribution of pathogens causing typical syndromes, drug sensitivity patterns of common STD pathogens, and case management practices of health-care providers.

IMPLEMENTATION OF STD SURVEILLANCE

There are two different types of surveillance data needed to monitor an STD program:

- Data to monitor the magnitude and regional distribution of STDs or STD syndromes
- Data to define and monitor effective diagnostic and therapeutic procedures

The following principles apply to both types:

- **Feasibility.** The STD surveillance has to be adapted to a health system's structure and capacity.
- **Continuity.** Changes in data collection methods should be kept to a minimum to accurately assess trends over time.
- **Standardization.** If the information is to be meaningful, standardized procedures must be used to collect data.
- **Confidentiality.** A breach in confidentiality, a basic principle of medicine, will deter patients from seeking health care.
- **Consistency.** Consistent data collection is critical and requires complete cooperation from health-care workers.
- **Feedback.** It is important that timely feedback (through meetings, newsletters, etc.) be provided to health-care workers.

MONITORING THE MAGNITUDE AND REGIONAL DISTRIBUTION

To obtain meaningful results, only major clinics with a good coverage of the respective catchment population should be selected as sentinel sites. Systematic data collection should be based on syndromes such as discharge or genital ulcers, and clear case definitions have to be developed.

DATA FOR THE DEVELOPMENT AND MONITORING OF CASE MANAGEMENT PROCEDURES

The information that is needed to develop and monitor case management procedures includes data about the relative frequency of the different STD pathogens, about their antimicrobial sensitivity and about management of STD patients by health-care providers.

DATA ANALYSIS AND FEEDBACK

To control for general changes in health-care-seeking behavior, data analysis should include trends in the number of patients with STDs or specific syndromes, and the rates of these patients compared to the total number of attendances.

GUIDELINES FOR THE INTERPRETATION OF THE RESULTS

As a program's STD services improve, it can be expected that more STD patients will be attracted to it and the number of reports will increase. This, then, would reflect the program's implementation and not an increase in STD incidence in the community. This is one of many factors to be considered when interpreting data, so as not to lead to inaccurate conclusions.

INTRODUCTION

For several decades, in many developing countries, sexually transmitted infections and diseases (STDs) caused by bacterial, mycotic and protozoal agents have ranked among the top five diseases for which adults seek health-care services. STDs and HIV have been found to be the second most important cause for the overall disease burden in young adult women (15 to 44 years of age) in the developing world.[1] The control of STDs pose a serious challenge and create an urgent need for countries to design, implement, monitor and improve public health programs for STD prevention and control.

Basic information on the frequency and distribution of diseases as well as patterns in the population are critical when planning and monitoring an STD program. Such data is collected by a disease surveillance system, which includes both specific studies and ongoing routine surveillance activities.

This chapter provides recommendations for the development of STD surveillance systems as part of national STD control programs. The guidelines discuss the basic strategies of STD surveillance for adaptation to the country-specific situations.

OBJECTIVES OF STD SURVEILLANCE

In most areas, etiologic diagnosis of STDs is not possible due to limited laboratory resources. Consequently, the management of a patient is usually based on the recognition of the syndrome and other factors such as risk assessment *(see Chapter 8)*. The decision on treatment schemes for the syndromic approach must be based on information about the frequency of the different pathogens in the population served.

Drug resistant strains are an increasing problem in many areas (penicillinase producing *Neisseria gonorrhoeae* strains are the cause of up to 80 percent of all gonorrhea cases in some areas). Therefore, resistance patterns and the expected number of cases have to be taken into account when deciding on STD treatment and when planning on drug supplies *(see Chapters 7 and 12)*.

The link between disease distribution and antimicrobial sensitivity data and STD management decisions is obvious and well accepted. However, often health-care providers forget that support by decision makers and, consequently, the availability of resources are critical to the situation's improvement. This includes the strengthening of health-care facilities (staff and diagnostic resources), a consistent supply with effective drugs and training for health-care providers. It is also important to monitor the program in order to reinforce, support and strengthen it.

Additional data are needed to monitor behavior changes and program implementation activities. This might mean periodic surveys on health-care-seeking behavior or monitoring condom distribution or training of health-care providers. This additional data complements surveillance data *(see Table 1 on the following page)*. For example, in many countries a substantial number of patients with an STD seek health care outside the established public sector health facilities. If there is no information about changes in health-care-seeking (e.g., due to the improvement of the services), the collected data on STD cases cannot be interpreted.

Objectives of STD Surveillance

The main objectives of STD surveillance are:

- Estimating the magnitude of the STD problem: to define the resources needed and raise awareness in decision makers to obtain the necessary support (advocacy)
- Measuring frequency, distribution and antimicrobial sensitivity of STD pathogens: to define and monitor effective diagnostic and therapeutic procedures
- Monitoring trends, to reinforce political support, and to monitor and improve the existing program

Table 1

INFORMATION NEEDED FOR STD PROGRAM MANAGEMENT

Advocacy	**Support by decision makers** (ongoing)	◆ Information about the magnitude of the problem Cost-benefit	Review of existing data Rapid assessment studies Specific surveys Routine surveillance Cost-benefit studies/calculations
Case management	■ **Planning and implementing of program activities** ■ Health care facilities	◆ Magnitude of the problem, regional distribution (epicentres) ◆● Identification of high risk populations ● Health care seeking behavior ● Health providers behavior ● Importance of non public sector	Review of existing data Rapid assessment studies Specific surveys Behavioral studies
	■ Effective diagnostic and treatment procedures	◆ Frequency of the different pathogens in the different areas/populations ◆ Drug resistance patterns	Review of existing data Rapid assessment studies Specific surveys
	■ **Evaluation and improvement of the program** ■ Case management procedures ■ Health-seeking behavior	◆● Information about trends over time (frequency and distribution of STD, health-care-seeking behavior)	Specific surveys Routine surveillance Behavioral studies
Primary prevention/ education	■ **Planning and implementing of program activities** ■ Definition of target populations ■ Development of effective interventions strategies	◆ Distribution of diseases by sex, age, and region ◆● Identification of high risk populations ● Identification of behavioral determinants	Review of existing data Rapid assessment studies Specific surveys Behavioral studies
	■ **Evaluation and improvement of prevention activities**	◆● Information about trends in risk behavior and the frequency of STD	Specific surveys Routine surveillance Behavioral studies

◆ *Information about the frequency and distribution of STD (including distribution of pathogens and drug sensitivity)*
● *Health services and behavioral studies (health care seeking behavior, risk behavior, behavioral determinants)*
Specific surveys/rapid assessment studies include: studies on the distribution and frequency of pathogens, syndromes, drug resistance

TYPES OF SURVEILLANCE

In general, there are three types of disease surveillance:

- Passive surveillance
- Enhanced surveillance in sentinel sites and populations
- Specific surveys

(Table 2 provides an overview of the methods, advantages and disadvantages of the different surveillance systems.)

PASSIVE SURVEILLANCE

Required by law in many countries, routine case reporting by health facilities of specific STDs is an example of classic surveillance. In theory, such a system yields a precise overview about STD prevalence as well as basic sociodemographic data. However, there are major deficiencies in passive surveillance systems. In countries with limited resources, the proportion of

Table 2:

KEY POINTS ABOUT THE DIFFERENT TYPES OF STD SURVEILLANCE

Study Population	Entire population	Selected sites such as: ▪ antenatal care units ▪ family planning centers ▪ blood banks ▪ military ▪ primary health care clinics ▪ GYN clinics ▪ STD clinics ▪ Specific laboratories	Random, or special samples
Methods	▪ Case notification	▪ Case notification ▪ Routine screening	▪ Sero-surveys ▪ Studies on drug sensitivity ▪ Risk assessment studies, Behavioral studies ▪ Outreach ▪ Health-care-seeking behavior
Information obtained	▪ Measurement of prevalence and incidence in the entire population	▪ Measurement of magnitude ▪ Measurement of trends	▪ Point prevalence ▪ Rapid assessment ▪ Patterns of pathogens ▪ Drug sensitivity ▪ Health care seeking/risk behavior
Advantages	▪ Surveillance of entire population	▪ Manageable ▪ Flexible ▪ Specific studies (resistance patterns) can easily be added	▪ Flexible ▪ Possible in areas with extremely limited resources ▪ Studies in specific populations (core groups) ▪ Facilitates interventions
Disadvantages	Unrepresentative due to ▪ Under reporting ▪ Underdetection ▪ Misclassification ▪ Not flexible ▪ Hard to evaluate ▪ Legislative or regulatory requirements Due to these problems, trends are difficult to interpret	Possible bias due to ▪ nonrepresentative sites ▪ changes in structure, accessibility and acceptability of sites Possible biases (health-care-seeking behavior) have to be taken into account when interpreting trends	▪ Random samples are extremely difficult to conduct
Cost-benefit	Low	High	Random samples surveys: Low Specific sample surveys: High
Strategies	▪ Legislative or regulatory requirements ▪ Development of standard forms ▪ Clear case definitions ▪ Feedback at each level	▪ Selection of representative and cooperative sites ▪ Development of protocols, case definitions, standard forms ▪ Enhance clinical and laboratory capability (training, technical support) ▪ Feedback at each level	▪ Development of protocols ▪ Selection of the respective sites/regions ▪ Implementation of a reference center/laboratory ▪ Feedback at each level
Recommendations	Useful for rare diseases with a simple, clear, and unequivocal case definition, if there is a high probability that a person with such a disease would be seen at some point in a health care facility cooperating with the health authorities. First choice if objective is the eradication of a specific disease (rather than decreasing the incidence)	Sentinel surveillance is an appropriate tool for the surveillance of STD with a high cost-benefit rate. The sentinel sites with well trained staff and good resources can serve as reference centers in the respective regions.	Useful to obtain an estimate about frequency and distribution of STD in a given population. Can complement and evaluate other surveillance activities. Instrument to measure prevalence in high risk/core groups. Such studies can also facilitate interventions (e.g. education, condom distribution)

STD cases reported to the respective health authorities is low due to underdetection, misclassification and under reporting.

It is estimated that less than 20 percent of the total number of STD cases are reported. Even more important, reporting is not systematic. Quantity and quality of the reports are irregular and the population covered by the system, the denominator, is usually unknown and may change substantially. Therefore, it may be impossible to extrapolate or generalize from the available data, and neither information on the magnitude or trends over time can be derived from it. As such, these surveillance systems do not yield useful managerial data for STD control programs.

Passive disease surveillance is used to monitor relatively rare sequelae of diseases that result from failures of the health-care system (e.g., due to limited resources in diagnostics or drugs). In this situation, passive case reporting is used to detect as many failures as possible to indicate the system's performance rather than to measure the incidence of the underlying disease, serving as a useful tool for improving the program. For example, congenital syphilis is a relatively rare complication of active syphilis in pregnant women. But it can be completely prevented if all pregnant women are screened for syphilis (case detection) and effective treatment is given to those who test positive.

Passive Surveillance

- Can be useful for the reporting of sequelae of STDS, indicating failure in health-care procedures (e.g., congenital syphilis)
- Does not yield the information needed for the planning and monitoring of STD control programs
- Existing passive surveillance systems should be incorporated into more reliable and cost-effective surveillance systems

Enhanced Surveillance in Sentinel Sites and Populations

In order to plan and monitor a program, reliable estimates of the problem's magnitude and trends over time are needed. It is not necessary to collect data about all cases and all diseases to obtain this information. Sufficiently reliable results can be obtained, assuming that indicator diseases or syndromes and representative facilities or populations can be defined.

There is a major advantage to having an enhanced surveillance system in sentinel sites and populations. Due to active cooperation and systematic data collection from a limited number of facilities, higher quality and more consistent information are obtained. At the same time, the costs of such a system are kept to a minimum because data collection is based on existing resources. However, since a particular site's information only represents the population it serves, sites must be chosen with care and the data must be interpreted with limitations kept in mind.

Sentinel Sites

To obtain reliable results, sentinel sites should do the following:

- Represent all geographic areas, both rural and urban
- Include facilities from all sectors that provide STD care

- Include sites representative of the population in order to monitor the magnitude and trends (e.g., antenatal clinic (ANC) attendees)
- Include sites representative of specialized clinics to monitor case management procedures (STD clinics)
- Have basic and consistent information about the populations represented (denominators)

To allow for trend interpretation, the total number of patients seen by a specific facility and the number of diseases or syndromes seen in the same period should be reported. As a rule, this information is collected by sites and is readily available.

Many countries have specialized STD service facilities. Generally well equipped, often they participate in some surveillance activities. These sites can be used to collect information needed for defining diagnostic and treatment schemes, including the distribution of pathogens (etiologic diagnosis) and, in specific surveys, antimicrobial sensitivity. Since the regional variability is limited for the distribution of the common STD pathogens and their antimicrobial sensitivity, the information obtained in a small number of these specialized facilities may be applied to other regions of a country and used for the development of national guidelines. However, these facilities usually cover only a small number of all STD patients. The population covered by these facilities and, thus, the denominators are unknown. Therefore, data collected in these facilities should not be used to estimate the magnitude of the problem or trends over time.

To overcome these problems, facilities delivering general health care such as primary health-care (PHC) centers or general outpatient departments (OPD) should be included in the sentinel system. In countries where many patients seek health care in the private sector, these facilities should be included if possible.

However, including private sector health-care sites/providers in a disease surveillance system may be difficult. In a country with a weak public health system, many patients seek health care in the unaccredited sector. As a result, it may be very difficult to obtain reliable results for the total population. But, if basic information on health-care seeking behavior is available that can assess the underestimation, such a system can still yield meaningful results in interpreting time trends.

Sentinel Populations

Another useful source for STD surveillance data are populations that seek health care or visit potential sentinel sites for reasons unrelated to STDs or other specific diseases. One important population group that is both accessible and fairly representative of the general population are pregnant women attending ANC clinics. For the collection of STD surveillance data, this population has the following advantages:

- Most pregnant women attend ANC services at some point during pregnancy (representative sample, little bias).
- STD examinations/testing can be included fairly easily in the routine procedures (costs, consistency).
- Systematic STD screening/case finding and cure have a direct impact on the health of the mothers and their children (elimination of congenital syphilis).
- This population is comparably stable over time (monitoring of trends).

Thus, routine case finding of active syphilis in pregnant women *(see Chapter 9),* is an excellent source of STD surveillance data. Routine case finding of other STDs such as chlamydial infection or gonorrhea can be added either as an ongoing activity or in specific surveys over defined periods of time *(see next section and Appendix 2)* where possible.

One disadvantage of ANC attenders as a sentinel population is that data collected in pregnant women usually underestimate the actual situation in the general population in the reproductive health ages. Pregnant women are, on average, more likely to live in stable partnerships. High-risk populations such as commer-

Sentinel Surveillance

Surveillance in sentinel sites and populations has the following advantages in STD control programs:

- Cooperation with a limited number of sites allows the systematic and consistent collection of data.
- Flexibility allows for additional studies to be added without changing the basic structure.
- Existing structures (e.g., passive reporting systems, research activities) can be used and strengthened.
- It can be started in a limited number of sites where training, manpower and resources are available.

In order to yield meaningful data, the sentinel sites and populations should do the following:

- Represent the population served by the specific facility
- Be selected thoughtfully
- Represent the different regions and population groups of a country

cial sex workers (CSWs) are underrepresented in this group. In addition, STDs are a major cause of infertility. Since infertile women are not covered by this sample, this also may lead to an underestimation of the real situation. These limitations have to be taken into account when interpreting the results.

Other groups that have been used as sentinel populations are blood donors and military recruits. However, the sociodemographic structure of blood donors is usually not well-known and may vary substantially. Military recruits might not be representative of the larger population due to age, living situation and the recruitment process. The interpretation of the results of STD screening in these populations may be problematic.

Specific Surveys

In addition to disease surveillance from data collected during routine health-care delivery, specific surveys also can be conducted to obtain programmatic information on STD. Such studies are conducted during defined time periods and may be repeated if appropriate.

One way to measure STD prevalence in the general population is by a survey of a random sample of the population that includes STD examinations/testing. Such surveys are extremely difficult to conduct, expensive and may not be acceptable by the population. However, they are increasingly feasible with the availability of urine-based tests and self-administered swabs.

Surveys in specific subgroups of the population may yield useful results for the planning and monitoring of STD control programs. If no reliable information about the magnitude of the problem and the distribution of STDs is available, rapid assessment studies in accessible populations (e.g. pregnant women, PHC clinic attendees) may yield a sufficiently reliable overview within a limited time period and thus the information needed for the planning of an STD program. Such data also can be used to validate existing reporting systems. (Design details for these studies can be found in Appendix 2.)

Besides assessing STDs in the population, specific surveys have to be performed to measure prevalence and incidence in high-risk populations such as CSWs or truck drivers. These populations are usually not seen in general health-care facilities or, if they use the existing facilities, biases in the health-care seeking behavior in these populations are unknown and systematic data collection is not possible. Thus, studies in general health-care facilities will underestimate the overall burden of STD.

Furthermore, intervention strategies that focus on these core groups play an important role in an STD control program. The detection of groups with high prevalence rates and the monitoring of trends may help in defining and evaluating such strategies. However, if there are no structures in place such as special clinics or outreach activities, those structures will have to be developed first and such studies will not be part of regular disease surveillance activities.

In areas where etiologic diagnosis of STDs is difficult due to limited resources and the diagnosis of STDs is made on the basis of typical syndromes, specific studies have to be performed to determine the common pathogens causing the syndromes. This information is critical in developing and monitoring case management recommendations. The same is true for antimicrobial sensitivity of the common pathogens. However, the patterns of pathogens and drug resistance usually do not vary dramatically between neighboring regions or within short periods of time, and it is sufficient if such studies are performed in a limited number of specialized sites once per year or biannually.

In addition to specific studies on STD distribution and the antimicrobial sensitivity of the respective pathogens, behavioral studies may yield important information for interpreting disease surveillance data (health-care seeking) and for the planning and monitoring of primary prevention strategies (risk determinants). However, these studies are usually complex and strongly dependent on the respective societal settings. They will not be discussed in detail in this chapter.

Specific Surveys

Specific surveys in limited samples over a limited time period are useful in obtaining a first assessment of the situation. they are the most cost-effective measure for determining the following:

- Prevalence of STDs in specific subgroups of the population
- Distribution of pathogens causing typical syndromes
- Drug sensitivity patterns of common STD pathogens
- Case management practices of health-care providers

These surveys complement ongoing surveillance activities on the frequency of STD in the population.

IMPLEMENTATION OF STD SURVEILLANCE

There are two different types of surveillance data needed to monitor an STD program:

- Data to monitor the magnitude and regional distribution of STDs or STD syndromes
- Data to define and monitor effective diagnostic and therapeutic procedures

An STD surveillance system should be an integral part of an STD control program and the data collection should interfere with the routine case management procedures as little as possible. Only essential data should be collected. Ideally, data collected for STD surveillance should be part of the routine case management procedures. In many places, surveillance activities may even be a useful tool to promote and monitor the implementation of standardized case management as part of an STD control program.

Although the type of data and the collection requirements differ for the purposes outlined above, the following principles apply to both:

- **Feasibility.** The STD surveillance has to be adapted to the structure and capacity of the health system in a country, taking into consideration available resources, staff skills and diagnostics. It is better to have a simple system that works than a complex system that does not work. There is often a tendency to increase the volume of data collected on the grounds that the extra information might be useful for some other purpose. This, however, inevitably increases the complexity of reporting forms and the effort required by the reporter. As a result, the chances that reporting will be incomplete because it is considered too cumbersome are increased. Additionally, data management and analysis also may become too complex. If more detailed information is needed, specific studies in selected sites are recommended.
- **Continuity.** To accurately assess trends over time, changes in data collection methods should be kept to a minimum. However, developments in health care might make changes in the surveillance system possible or necessary. Introducing more specific reporting is not a problem. For example, better resources may allow the specific reporting of gonococcal and nongonococcal urethritis instead of urethral discharge. Combining the information on these specific diagnoses will give information on total urethritis patients and allow for comparison to earlier data.
- **Standardization.** It is critical that data be collected using standardized procedures if the information is to be meaningful. Therefore, clear case definitions and training of all data providers are necessary. Procedures should be developed that can be met by all sites and areas in the system, even the weakest ones.

Recommendations for STD Surveillance Systems

- Sentinel surveillance in a limited number of selected sites is the most efficient way to collect the information needed for managerial decisions. Such a system is flexible, and specific surveys can be included if appropriate without interfering with the basic structure. The sentinel sites should represent different regions of sectors that deliver health and STD care.
- The ongoing disease surveillance activities should be complemented by specific surveys, including surveys in target populations such as prostitutes, and surveys for biologic information such as distribution of pathogens and drug sensitivity.
- Existing structures (e.g., cooperation in passive surveillance systems or specific research projects) should be used for the sentinel system if possible.
- STD surveillance should be an integrated part of the STD control program and not stand alone. Only information that can be used for planning and monitoring the program should be collected.
- STD surveillance activities can be used as a tool for training and monitoring the implementation of the STD control program.

- **Confidentiality.** Everyone involved in health care is bound to the principle of medical confidentiality. A breach in confidentiality will deter patients from seeking health care, and may severely affect the program's efficacy. The protection of human rights is a critical element of an STD program. Reporting within the surveillance system should be strictly anonymous and can usually be based on aggregated data.
- **Consistency.** Consistent data collection is critical and requires complete cooperation from health-care workers (HCWs). To obtain such cooperation, it is

important that (1) HCWs involved in the reporting system understand the need for the data collection; (2) HCWs are given feedback; (3) the reporting procedures are simple; and (4) responsibilities and lines of communication are clear.

- **Feedback.** Timely feedback to HCWs is critical in any surveillance system. The feedback should include (1) all personnel that are involved in the surveillance system; (2) written material (e.g., a regular newsletter) and (3) personal communication (e.g., regular meetings) to discuss the results and possible problems at all levels.

Monitoring the Magnitude and Regional Distribution

Site selection

Specialized STD clinics usually cover only a small proportion of STD patients. Furthermore, the population seen by these facilities, the denominators, is unknown. Thus, data collected there cannot be used to estimate the problem's magnitude and trends over time. To measure STD levels, regional distribution and trends, health-care facilities with a known catchment population should be included in a sentinel surveillance system. These include general outpatient departments (OPDs), primary health-care facilities (PHCs) and, in some countries, general practitioners (GPs). Although it is often quite difficult to include the private sector in sentinel surveillance, the possibility of enrolling such facilities should be explored. In addition, the issue of motivating individuals in this part of the health-care system should be addressed.

Antenatal care clinics (ANCs) are an important source for data collection. Most pregnant women attend ANC services at some point during pregnancy and, consequently, are fairly representative of low-risk sexually active women. Since this population is relatively stable, its surveillance allows for the interpretation of STD incidence trends.

Criteria for selecting the respective sites include location, staff training level, degree of commitment by health-care providers and patient load. To obtain meaningful results, only major clinics with a good coverage of the respective catchment population should be selected as sentinel sites. In general, the total patient load of a selected site should exceed 1,000 patients per month. Since some sites cover much larger patient populations, it might be necessary to follow a predefined sampling scheme for reporting (e.g., every first and third week of the month). However, for consistent results it might be better and easier to collect the data on an ongoing basis.

One of the major advantages of sentinel surveillance is that once the principal procedures have been defined, data collection can begin in a very limited number of sites. Other sites can be added gradually after staff have been adequately trained, the necessary resources have been made available and cooperation with the health authorities have been established.

The selected sites should be located in different areas of the country. At a minimum, they should include at least one primary health-care facility and one antenatal care facility in both an urban and a rural area. With advances in the program, the number of sites can be increased gradually until all major regions of a country are covered, without interfering with the basic structure of the system.

However, the system should only be expanded if the infrastructure at all levels (including data collection and analysis at the central level), channels of communication and feedback are available. Delays in the flow of information due to work overload or a weak structure will discourage the data providers and lead to inconsistencies in the system.

Data collection

In most countries, the diagnostic and laboratory resources are very limited in health-care facilities. Thus, the diagnosis of STDs is usually based on recognizing syndromes such as discharge or genital ulcers. Systematic data collection should be based on these syndromes and clear-case definitions (algorithms for the syndromic approach) have to be developed.

In facilities where more detailed diagnosis is possible (e.g., distinguishing between gonococcal urethritis and nongonococcal urethritis instead of the broad urethral discharge diagnosis), data collection should be performed so that the most basic information can be derived as the common denominator, in this case combining both forms of urethritis into the category of urethral discharge.

In general, basic patterns in disease distribution can be recognized sufficiently through stratification by sex and two age groups. In Appendix I, samples of tally sheets are included that allow the data to be collected by the health-care provider without the need for any additional infrastructure. For each patient with an STD or with the respective syndrome a tick (checkmark in a box on a card) is made in the respective field. To make sure that rates can be calculated accurately, only the first visit of a patient with a specific syndrome should be marked as such. If a patient is diagnosed with more than one syndrome, a tick should be made for each diagnosis. This may lead to a slight overestimation of the problem. However, it will yield a more reliable estimate about the frequency and trends of the different diseases. At the end of a month the respective fields are summed up and the totals are transferred to the summary sheet. To estimate caseload attributable to STDs, the total number of patients seen in the respective period also should be marked. The same tally sheets could be used to collect the information out of patient records at a central point within a specific facility.

The tally sheets are examples of how surveillance data can be collected simply and systematically. The syndrome and age groupings included in the surveillance system may have to be adapted to the specific situation in a country. If more detailed information is required, the data should be collected in specific surveys that do not interfere with routine surveillance procedures.

The systematic collection of syphilis screening results among antenatal clinic women is a useful measure for monitoring syphilis rates in sexually active women. An example of a tally sheet is included in Appendix 1. Similar to surveillance in a primary health-care setting, only the first test during a pregnancy should be considered, assuming more than one test is performed during the pregnancy. Since this group is fairly representative of the general female population, routine case findings of other STDs (e.g., gonorrhea, chlamydial infection or trichomoniasis) may yield reliable information about the overall impact of STDs in the population (including asymptomatic infections). However, routine case findings of these diseases as an ongoing activity is usually not possible due to limited laboratory resources and lack of trained personnel. In such a case it may be useful to perform specific studies on a sample of women once a year or less frequently.

If routine case finding and treatment of syphilis in pregnant women are part of a national program (e.g., STD control program, maternal and child health (MCH) program, control/elimination of congenital syphilis), universal case reporting of congenital syphilis may yield useful information on the performance of health-care procedures and how well the specific program has been implemented. However, these data are not useful in measuring magnitude and trends in active syphilis.

Data for the Development and Monitoring of Case Management Procedures

The information that is needed to develop and monitor case management procedures includes data about the relative frequency of the different STD pathogens, about their antimicrobial sensitivity and

about management of STD patients by health-care providers. It is obvious that biologic data can only be collected in facilities where etiologic diagnosis and drug sensitivity testing are possible. This is usually the case in specialized STD facilities and reference centers.

Site selection

There is limited variability between neighboring regions in the basic distribution patterns of different diseases and antimicrobial sensitivity of the respective pathogens. Therefore, for programmatic decisions (development and monitoring of national diagnostic and treatment guidelines), it is sufficient to conduct the necessary studies in a very limited number of facilities. If possible, one reference center in each major metropolitan area of a country should be included in the surveillance system. The criteria for the selection of the sites for data collection include the resource availability, staff training, health-care worker commitment, and patient workload.

Data collection

Distribution of STD pathogen

If specialized STD centers are in place where etiologic diagnosis of STDs is performed with all patients, the systematic collection of the data can be performed as an ongoing surveillance activity. This is similar to the data collection in primary health-care facilities. An example of a simple tally sheet for etiologic diagnosis and reporting of specific diseases is included in Appendix 1. The disease categories included in such a form may have to be adapted to each country's situation.

Etiologies of various STD syndromes do not change rapidly or vary widely in regions. Consequently, it is sufficient to collect etiologic information with specific surveys once a year or less frequently.

Testing of antimicrobial sensitivity of common STD pathogens

Testing of antimicrobial sensitivity should be performed in *Neisseria gonorrhoeae* isolates since drug resistance has been reported to be common in this pathogen *(see Chapter 12)*. Drug resistance is also common in *Haemophilus ducreyi,* but antibiotic susceptibility testing is quite difficult.

DATA ANALYSIS AND FEEDBACK

The data should be communicated monthly to the respective health authority using prepared forms and clearly defined reporting lines. Analysis of the data should be performed in regular intervals at both the local/regional and central levels. To control for general changes in health-care-seeking behavior, data analysis should include trends in the numbers of patients with STDs or specific syndromes and the rates of these patients compared to the total number of attendances. The analysis should be performed separately for each type of facility. To obtain background information that may help in interpreting the results, close cooperation with the data providers is essential. For example, changes in service may be the reason for an increase in the number of attendances. Some examples for data analysis and results interpretation are given below.

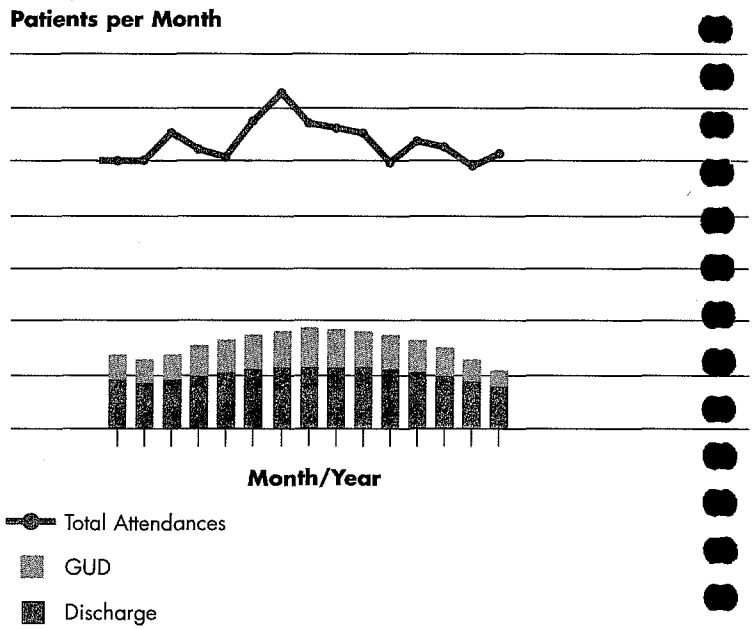
To renew motivation and obtain the cooperation of health-care providers, regular feedback is a critical part of any surveillance system. Only if personnel understand the purpose of collecting information can consistent reporting be achieved. In addition to printed materials such as quarterly newsletters, regular meetings with the personnel all levels to discuss problems should be an integral part of surveillance activities. Such meetings are also a useful tool in monitoring the program implementation. They may further motivate health-care workers and yield information needed to make changes in the program.

In addition to this "center-periphery" feedback, activities within the different sites can help personnel involved in the reporting procedures to become more motivated.

For example, displaying bar charts is a good way to show that data is used and that everybody is working to meet the objective of monitoring the program activities. The bar charts should include the number of STD patients and the distribution of the diseases in the population served. They also may include the number of treatments given or the distribution by sex and age group, etc. The bar charts should be updated monthly *(an example is shown below).*

Example 1

Chart to Display Trends Within a Specific Facility



GUIDELINES FOR THE INTERPRETATION OF THE RESULTS

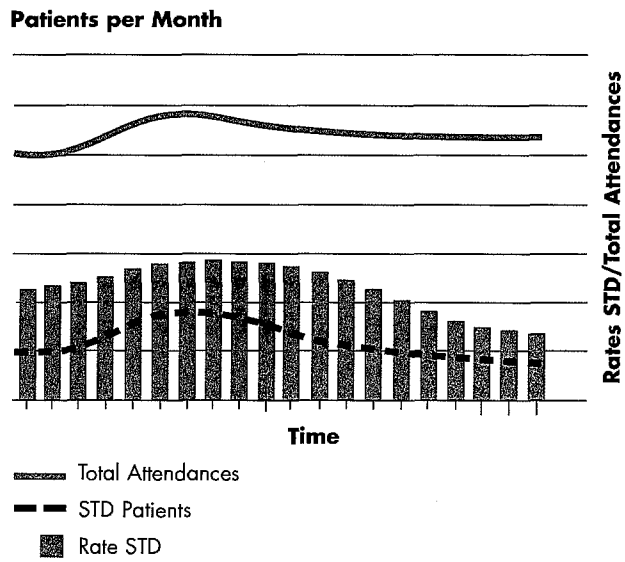
Two major objectives of an STD program are to improve STD services and promote health-care seeking behavior in populations at risk for an STD. Therefore, it can be expected that more STD patients will be attracted to the improved STD services, and the number of reports will increase initially. This increase in STD patients would reflect the program's implementation and not an increase in STD incidence in the community.

In the following section, examples of observed trends in STD surveillance data are given for different scenarios. The figures are meant to show typical developments. The scales for the number of STD cases and total number of attendances are chosen arbitrarily and will differ for specific countries.

Scenario 1: *Rural primary health-care (PHC) center after introduction of integrated STD care using the syndromic approach.*

The data are collected using the STD monthly tally sheet. The number of total attendances per month is depicted in the solid line; the number of initial visits of depicted in the dashed line. The bars "patients (with STD syndromes) per month" is illustrative of the rate of STD patients/total attendances.

Scenario 1



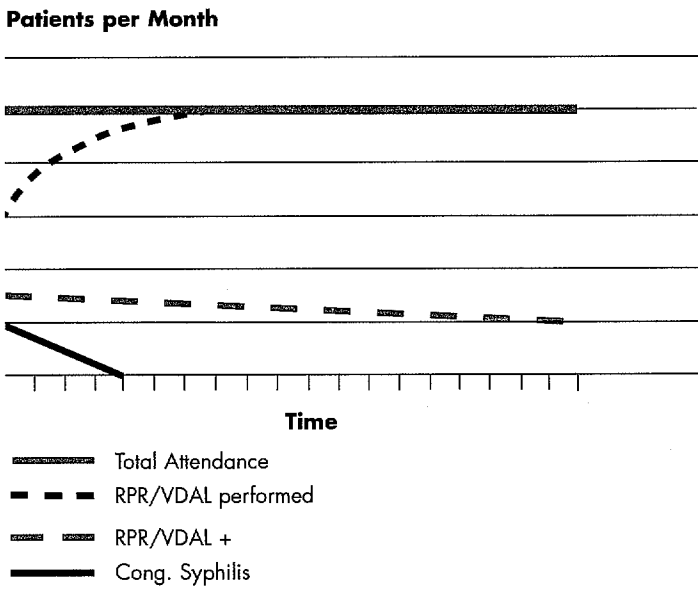
As can be seen, the number of attendances increased initially due to an increase in the number of STD patients, followed by a decrease in both lines at different rates. The initial increase could be explained by improved services in the facility (e.g., effective treatment, longer hours) and changes in the health-care seeking of the patients at risk for STDs. The following decrease will first reflect the decrease of STD patients in the community due to the effective cure of patients with an STD, and in the medium term be an indicator for a real decrease in the incidence due to an effective program. The decrease in the prevalence/incidence of STDs in the population served by this facility is shown by a decreasing rate (STD patients/total number of attendances) of STD patients (bars).

Scenario 2: *Periurban ANC clinic after the introduction of routine syphilis case-finding and treatment.*

The data are collected using the respective tally sheet. The lighter solid line reflects the total number of pregnant women per month visiting the facility. The total number of syphilis screening tests and the number of positive tests are depicted in the small-dashed and large-dashed lines, respectively. The number of congenital syphilis cases during the same period is indicated by the dark solid line.

As to be expected for an ANC clinic with high coverage of the population, there was no major change in the total number of attendances over time. Due to the implementation of the STD program, the number of performed RPR/VDRL tests increased initially until a relatively complete coverage had been achieved. The effective case finding and treatment of all women with positive syphilis serology, and the education of the women and their partners (where possible), led to a slow but steady decline in the number of women with active syphilis. The number of congenital syphilis cases declined at the same rate as RPR/VDRL screening was introduced. Little or no decline in the number of congenital syphilis cases with complete coverage of pregnant women with syphilis-screening tests would indicate ineffective treatment (e.g., drugs are unavailable, diagnosis and treatment are not provided during the first visit or the women are not returning for results and treatment).

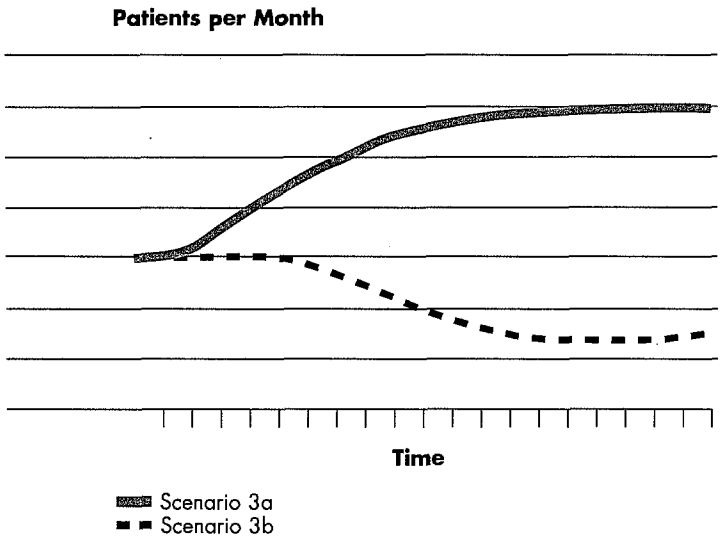
Scenario 2



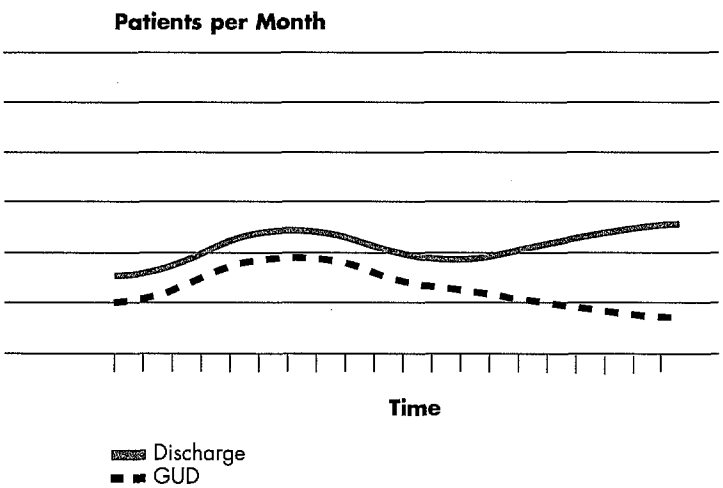
Scenario 3a and 3b: *Specialized STD clinic in an urban center after implementing a national STD control program.*

Data are collected using the respective tally sheets. Two developments that can occur after an effective STD control program is implemented are depicted. In scenario 3a, the improvement of services (e.g., due to longer clinic hours, better training of personnel and the inclusion of counseling) increased community acceptance of the clinic and led to a clear increase in the number of STD patients per month. In scenario 3b, the decrease of patients could be due to a smaller number of referred patients from a nearby PHC center, whose staff were trained recently to treat STDs using the syndromic approach. Such changes in health-care procedures have to be taken into account when interpreting the results from a specific facility.

Scenario 3a and 3b



Scenario 4



Scenario 4: *Rural PHC center after introducing integrated STD care using syndromic approach.*

Data are collected using the respective tally sheet. As can be seen, the number of patients with an STD syndrome increased, initially for patients with genital ulcers as well as those with discharge. This development may be due to an increase of STD patients following an improvement of services. However, the initial increase is followed by a steady decrease in the number of patients with a genital ulcer, but a second increase in patients with discharge. This development could signal an increase of drug resistant *Neisseria gonorrhoeae* strains.

Scenario 5: *STD patients in STD clinic in Nairobi, Kenya, 1988-1991.*[6] *(This example is taken from a real situation in an urban STD center.)*

The graph shows a typical situation and one that can be seen in other countries. After user fees were introduced in public clinics, the attendance rates for STD patients declined dramatically. Subsequent to resuming free services, the number of patients eventually increased to the original level. Obviously, these trends are "artificial" and not caused by real changes in the prevalence and incidence of STDs in the population.

Scenario 6: *Reported STD cases in men in Thailand 1967-1992.*[7]

This example is meant to illustrate a variety of complex factors that can influence surveillance data. The graph shows a rapid increase in STD reports from 1967 to 1980. This is followed by a dip in 1982, and then an increase and plateau between 1984 and 1987. After 1987, the number of reports drops dramatically. The major question is whether these trends mirror real changes in STD incidence or whether, and to what degree, other factors may have influenced their development.

To answer this question, additional information has to be considered. The initial increase in STD cases goes along with Thailand's rapid socioeconomic devel-

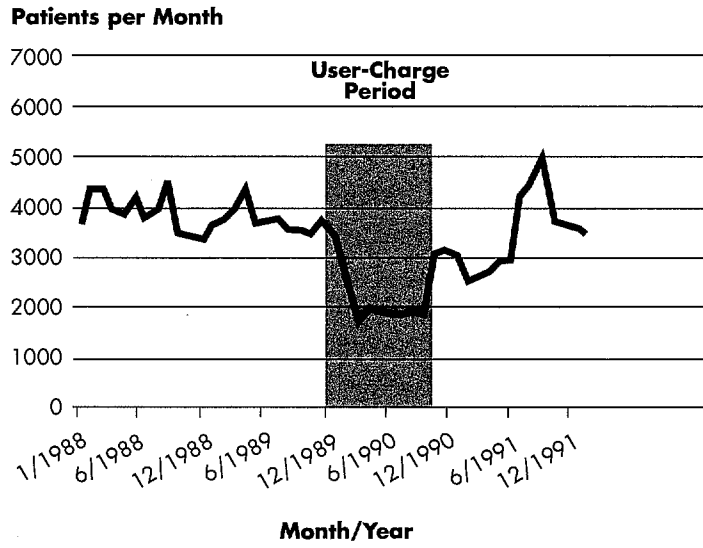
opment, industrialization with a heavy rural to urban migration and an expansion of the commercial sex industry. All three developments are well-defined factors for the spread of sexually transmitted diseases.

In addition to these socioeconomic factors, the emergence of penicillin-resistant gonorrhea, in the absence of effective and affordable treatment, increased from 7 percent in 1978 to 42 percent in 1981. Thus an increase in STD incidence seems to be quite plausible. However, apart from these socioeconomic, behavioral and biological factors, some of the increase reported after 1974 was artificial, resulting from a growing network of STD clinics and an expanded reporting system. The temporary drop between 1980 and 1984 resulted from major reorganizations in the Ministry of Health and the STD program. Since then, no changes in the system have occurred. Thus, it seems that the trends observed in the reports are based on real changes in the STD incidence. This is also supported by the fact that the dramatic decrease since 1987 parallels massive safer sex campaigns and promotion of condoms in brothels.

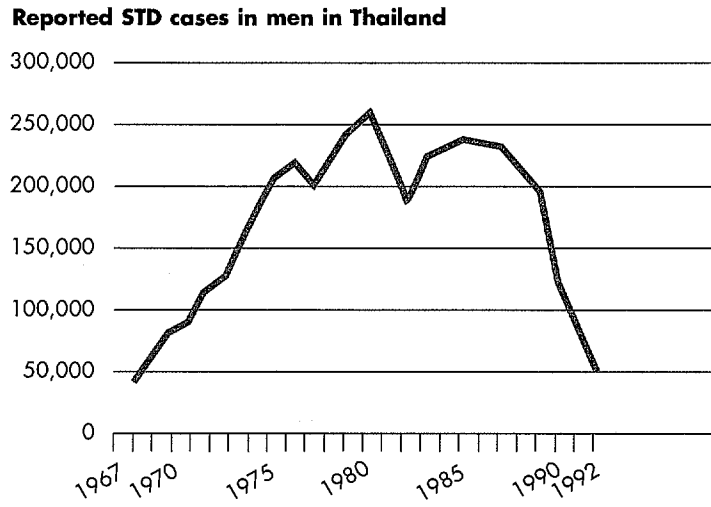
Similar decreases have been reported from specific areas where more detailed data collection and analysis were possible. Thus, in all likelihood, the observed decrease in STD reports really reflects a decrease in STD incidence. However, as shown above, trend interpretation must be done very carefully, taking into account a variety of possible factors that can obscure real developments.

Although all the scenarios just outlined show typical situations, other factors also can influence trends in health-care seeking behavior and have some impact on a program's efficacy. Thus, it is important that the results from different sites and studies be seen and interpreted together. However, the collection of additional information (e.g., number of referred patients in an STD clinic compared to patients who were not referred, data on changes in health-care-seeking behavior) might be necessary to accurately interpret observed trends.

Scenario 5



Scenario 6



APPENDIX 1

TALLY SHEETS

STD Monthly Tally Sheet

Month: _____ **Year:** _____ **Facility:** _____

For each initial visit of a patient with one of the following diagnoses make a tick in the appropriate field: 00000.
Initial visit is defined as the first consultation for an episode in this clinic.

Syndrome	Age	Tally Marks Males	Total
Genital Ulcer Male	15–24	00000 00000 00000 00000 00000 00000 00000 00000 00000 00000	
	≥ 25	00000 00000 00000 00000 00000 00000 00000 00000 00000 00000	
		Total GUD M	

Syndrome	Age	Tally Marks Females	Total
Genital Ulcer Female	15–24	00000 00000 00000 00000 00000 00000 00000 00000 00000 00000	
	≥ 25	00000 00000 00000 00000 00000 00000 00000 00000 00000 00000	
		Total GUD F	

Syndrome	Age	Tally Marks Males	Total
Urethral Discharge	15–24	00000 00000 00000 00000 00000 00000 00000 00000 00000 00000	
	≥ 25	00000 00000 00000 00000 00000 00000 00000 00000 00000 00000	
		Total Urethral Discharge	

Syndrome	Age	Tally Marks Females	Total
Vaginal Discharge	15–24	00000 00000 00000 00000 00000 00000 00000 00000 00000 00000	
	≥ 25	00000 00000 00000 00000 00000 00000 00000 00000 00000 00000	
		Total Vaginal Discharge	

At the beginning of each month sum up the last's month tally sheet(s) and transfer the totals to the monthly summary sheet.
If there has been no patient seen with a specific syndrome, put a zero in the respective total column.

Cut here and send the monthly summary sheet to _____

STD Monthly Summary Sheet

Month: _____ **Year:** _____ **Facility:** _____

Age	Genital Ulcer Males	Urethral Discharge	Genital Ulcer Females	Vaginal Discharge
15–24				
≥ 25				
Total				

Total Number of Patients ≥15 Years Seen in the Clinic	
Males (if possible)	
Females (if possible)	
Total	

Date: _____ **Signature:** _____

STD Monthly Tally Sheet (ANC/MCH Facilities)

Month: _____ **Year:** _____ **Facility:** _____

For each initial visit of a patient with one of the following diagnoses make a tick in the appropriate field: 00000.
Initial visit is defined as the first consultation for an episode/during pregnancy in this clinic.

	Age	Initial Visits	Total
Positive Syphilis Serology (RPR/VDRL)	15–24	00000 00000 00000 00000 00000 00000 00000 00000 00000 00000	
	≥ 25	00000 00000 00000 00000 00000 00000 00000 00000 00000 00000	
		Total RPR/VDRL positive	

Ophthalmia Neonatorum	00000 00000 00000 00000 00000 00000 00000 00000 00000 00000	

Congenital Syphilis	00000 00000 00000 00000 00000 00000 00000 00000 00000 00000	

At the beginning of each month sum up the last's month tally sheet(s) and transfer the totals to the monthly summary sheet.
If there has been no patient seen with a specific disease, put a zero in the respective total column.

Cut here and send the monthly summary sheet to _____

STD Monthly Tally Sheet (ANC/MCH Facilities)

Month: _____ **Year:** _____ **Facility:** _____

Age	Positive RPR/VDRL
15–24	
≥ 25	
Total	

Ophthalmia Neonatorum	Congenital Syphilis

Total Number of RPR/VDRL Tests Performed (≥ 15 years) (Only First Test During Pregnancy)	Total Number of Persons Seen in the Clinic (≥ 15 years)

Date: _____ **Signature:** _____

STD Monthly Tally Sheet (Etiologic Diagnosis)

Month: _____ **Year:** _____ **Facility:** _____

For each initial visit of a patient with one of the following diagnoses make a tick in the appropriate field: 00000.
Initial visit is defined as the first consultation for an episode in this clinic.

Syphilis

Age	Males	Total	Females	Total
Genital 15-24	00000 00000 00000 00000 00000 00000		00000 00000 00000 00000 00000 00000	
Ulcer ≥ 25	00000 00000 00000 00000 00000 00000		00000 00000 00000 00000 00000 00000	
	Total Syphilis M		**Total Syphilis F**	

Gonorrhea

Age	Males	Total	Females	Total
Genital 15-24	00000 00000 00000 00000 00000 00000		00000 00000 00000 00000 00000 00000	
Ulcer ≥ 25	00000 00000 00000 00000 00000 00000		00000 00000 00000 00000 00000 00000	
	Total Gonorrhea M		**Total Gonorrhea F**	

Chancroid

Age	Males	Total	Females	Total
Genital 15-24	00000 00000 00000 00000 00000 00000		00000 00000 00000 00000 00000 00000	
Ulcer ≥ 25	00000 00000 00000 00000 00000 00000		00000 00000 00000 00000 00000 00000	
	Total Chancroid M		**Total Chancroid F**	

Chlamydia Trachomatis Infection

Age	Males	Total	Females	Total
Genital 15-24	00000 00000 00000 00000 00000 00000		00000 00000 00000 00000 00000 00000	
Ulcer ≥ 25	00000 00000 00000 00000 00000 00000		00000 00000 00000 00000 00000 00000	
	Total CT M		**Total CT F**	

Herpes genitalia

Age	Males	Total	Females	Total
Genital 15-24	00000 00000 00000 00000 00000 00000		00000 00000 00000 00000 00000 00000	
Ulcer ≥ 25	00000 00000 00000 00000 00000 00000		00000 00000 00000 00000 00000 00000	
	Total Herpes M		**Total Herpes F**	

Trichomonas Infection

Age	Males	Total	Females	Total
Genital 15-24	00000 00000 00000 00000 00000 00000		00000 00000 00000 00000 00000 00000	
Ulcer ≥ 25	00000 00000 00000 00000 00000 00000		00000 00000 00000 00000 00000 00000	
	Total Trich M		**Total Trich F**	

Other/Unspecified GUD

Age	Males	Total	Females	Total
Genital 15-24	00000 00000 00000 00000 00000 00000		00000 00000 00000 00000 00000 00000	
Ulcer ≥ 25	00000 00000 00000 00000 00000 00000		00000 00000 00000 00000 00000 00000	
	Total Unspec GUD M		**Total Unspec GUD F**	

Total Unspec Disch M

Age	Males	Total	Females	Total
Genital 15-24	00000 00000 00000 00000 00000 00000		00000 00000 00000 00000 00000 00000	
Ulcer ≥ 25	00000 00000 00000 00000 00000 00000		00000 00000 00000 00000 00000 00000	
	Total Unspec Disch M		**Total Unspec Disch F**	

At the beginning of each month sum up the last's month tally sheet(s) and transfer the totals to the monthly summary sheet.
If there has been no patient seen with a specific disease, put a zero in the respective total column.

Cut here and send the monthly summary sheet to _____

STD Monthly Summary Sheet (Etiologic Diagnosis)

Month: _____ **Year:** _____ **Facility:** _____

Age	Syphilis		Chancroid		Herpes		Other/unsp GUD	
	M	F	M	F	M	F	M	F
15–24								
≥ 25								
Total								

Gonorrhea		Chlamydial Infection		Trich		Other/unsp GUD	
M	F	M	F	M	F	M	F

Total Number of Patients ≥ 15 Years Seen in the Clinic	
Males (if possible)	
Females (if possible)	
Total	

Date: _____ **Signature:** _____

APPENDIX 2: ASSESSMENT OF THE EPIDEMIOLOGICAL SITUATION OF STDS

INTRODUCTION

This section outlines methods for collecting over a short time period data on a country's epidemiological situation in regard to STDs. It does not include methods for assessing STD case management.

For the purpose of developing an STD control program, baseline data on the prevalence and incidence of STDs in a country is necessary. Protocols are outlined here to determine the following:

Protocol 1

- The proportion of adult attenders of health facilities diagnosed with STD or STD syndromes
- The distribution of various STD syndromes among adult attenders of health facilities

Protocol 2

- The proportion of pregnant women attending antenatal clinics with positive serology for syphilis

Protocol 3

- The etiology of common syndromes and the antibiotic sensitivity of *N. gonorrhoeae* and H. *ducreyi,* if appropriate

Protocol 4

- The prevalence of gonorrhea, chlamydial infection and trichomoniasis among women seen in health facilities who are not seeking STD care

Protocol 5

- The prevalence of various STDs among high-risk populations

Information obtained using protocols 1, 2, 4 and 5 will show the magnitude of the STD problem and the justification for an STD program. Data obtained using protocols 1 and 2 should have been gathered before the start of the program, but data from protocols 4 and 5 can be obtained as part of the STD program. Information on the etiology of syndromes and the microbial sensitivity (protocol 3) is needed to establish national guidelines for STD management that will be based on a syndromic approach. This information also can be collected as part of the STD program.

When no data exist and in the absence of the required research capability, data on syndrome prevalence and etiology and antimicrobial sensitivity may be obtained in neighboring countries. Comparisons may be made between similar geographic and social settings. However, as one of the first program implementation steps, every effort should be made to develop the necessary infrastructure for conducting the surveys described in this section.

METHODS

Protocol 1

To determine:

- *The proportion of adult attendees of health facilities diagnosed with STD or STD syndromes*
- *The distribution of various STD syndromes among adult attendees of health facilities*

Collection of Existing Data

First, one should look for STD data that may already exist. Data may be available on the total number of attendances and on attendances for STD care at health facilities.

Location. The following sectors should be evaluated as potential sources of data.

Public sector: some information on the caseload in the public sector (specialized STD clinics, hospital outpatient departments (OPDs) of other specialities, first level care including dispensaries, health centers, maternal and child health (MCH) and family planning (FP) clinics) may be available in the records of the epidemiology unit of the Ministry of Health (MOH). The types of reported STDs should be noted and whether they are reported on an etiologic or syndromic basis. Emphasis should be placed on urethral discharge in males, vaginal discharge and lower abdominal pain in women, and genital ulcers in both sexes. If data are reported on an etiologic basis it may be difficult to categorize it by the above syndromes. If reporting occurs by age group this information should also be obtained.

Private sector. This sector may provide STD care and may have data available of the same type as described above (total caseload, proportion of persons seeking STD care, number of diagnosed syndromes and distribution of syndromes, by sex and age group).

Results

Data collected in this way may give information on the caseload of adult patients attending a health facility for STD care and on the relative distribution of the various STD syndromes. When additional data are available on attendances at that facility for other reasons, the rank that STDs have among the diseases for which adults seek health care may be assessed.

Limitations

There are some limitations to using existing data. First, there is uncertainty about how complete the reporting has been. However, as is the case almost everywhere, it is expected that a surveillance system based on case notification will result in under-reporting.

Second, misclassification may have occurred. For example, there may be reports available on the number of cases of gonorrhea diagnosed in health facilities. As a rule, the diagnosis will have been made clinically and not on gonococcal detection, and the number probably reflects cases of urethral discharge in men. The number of syphilis cases may in fact be the number of patients seen with genital ulceration. Patients presenting with dysuria or vaginal discharge may have been classified as having urinary tract infections or received the diagnosis of "other," while, in fact, they have an STD.

Furthermore, there is usually under-detection because in most countries there is no case finding for men and women who are not seeking STD care. A severe rate of under-detection occurs due to the fact that many STD patients do not have symptoms or have nonspecific symptoms. However, under-detection also occurs in symptomatic persons seeking STD care due to both the lack of knowledge of STDs among health-care providers and the lack of diagnostic facilities.

Prospective Data Collection

The existing data on the number of persons seeking STD care in health facilities may be insufficient; and/or there may be inadequate data on the prevalence of STD syndromes. For example, there may be data on gonorrhea in males and on urinary tract infection in females, but no data on the total caseload of that health facility.

Even when good data are available, it may be decided that the data needs validation for decision making purposes. Therefore, a survey should be started to collect, prospectively, data on the number of individuals

who have an STD or an STD syndrome, the total number of patients seen in the health facility and the distribution of syndromes (e.g., genital ulceration in both sexes, urethral discharge in males, vaginal discharge and lower abdominal pain indicating pelvic inflammatory disease in women).

Study design

- **Location.** The locations for the prospective data collection can be urban and rural clinics, both public and private. Although it is not required, ideally they should be representive of the country. A minimum of five sites should be included in this survey. Preferably, clinics with a high attendance rate and a high coverage of adults (15 years and older) living in that area should be chosen.
- **Study population.** All adult men and women who attend the clinic during the study period should be included in the survey.
- **Duration of the survey and sample size.** The duration of the survey should be limited to a period of two to three months. The sample size will be the total number of adult attendances at the health facility. For example, if a clinic had 1,000 consultations per month and 3 percent to 20 percent of them were for STDs, after two months of surveillance there would be 60 to 400 syndromes to study in terms of the distribution by sex. This number should be regarded as a minimum since patients may have concurrent syndromes.
- **Training of health staff.** In order to collect good data, before starting, information should be given to the health staff about the aim of the survey and why a complete registration is needed. In addition, the health staff should be trained in how to examine patients and how to recognize STD syndromes.
- **Data collection.** Information should be collected on the following:
- The total number of consultations in the clinic for persons aged 15 and older, by sex
- The number of persons (also 15 years and older) by sex visiting the clinic with the following diagnosed syndromes: urethral discharge, vaginal discharge, genital ulcerations and lower abdominal pain

Results

Data will provide information on the caseload of patients attending a health facility for STD care, which will represent a percentage of the clinic's total attendances.

$$\text{PERCENT OF ADULT STD PATIENTS} = \frac{\text{ADULTS DIAGNOSED WITH STD}}{\text{TOTAL NUMBER OF ADULT ATTENDANCES}}$$

Data will also indicate the distribution of STD syndromes among those seeking STD care. When information is available on other diagnoses made at the facility, it will be possible to assess the rank that STDs have among the diseases for which adults seek treatment *(see Example 2).*

Data on STD syndrome incidence at the clinic level can be used to estimate the stock of drugs that are required *(see Chapter 7).* If the study clinics have been representative of the country, the data can be extrapolated into an estimation of the minimum amount of STD drugs needed for the whole public sector.

EXAMPLE: Assessment of the stock of drugs needed for the treatment of STD syndromes

In Zimbabwe, STD services are fully integrated at all levels of health-care facilities. It is estimated that nearly 75 percent of all STD patients are managed in the public sector. The estimated drug requirement for this sector is based on the estimated number of STD syndromes which, in turn, stems from the number of

reported syndromes. (See the Table 1 for the estimated costs of STD drugs in Zimbabwe during 1991.) Based on the figures in Table 1, the reported vaginal discharge cases are much lower than would be expected. This is because a large number of women with vaginal discharge seek help and are treated at primary care and MCH/FP clinics as well as at special gynecology and obstetrics clinics. Most of the time these cases are not reported and therefore not included in the calculations.

Limitations

A limitation of this study is that it may take some time before the health staff is properly trained. Another limitation is that only a small part of the adult population may go to this facility for health care. When most patients seek health care elsewhere (e.g., at non-accredited facilities), the information collected will have a very limited value in describing the magnitude of the STD problem in the country. Therefore, one should choose preferably those clinics with a high coverage of the population and interpret the data in light of the limitations of this type of survey.

Protocol 2

To determine the proportion of pregnant women attending antenatal clinics with positive serology for syphilis

A woman infected with syphilis can transmit the disease to her fetus *(see Chapter 9)*. Without treatment, maternal syphilis may cause abortion, stillbirth, prematurity, the delivery of an infant with clinical signs of congenital syphilis or the delivery of an apparently healthy baby who develops clinical signs of congenital syphilis over the next several months. Congenital syphilis is a serious but totally preventable disease and can be eliminated or reduced to a very low level. If pregnant women are serologically screened and maternal syphilis is adequately treated, the risk to the infant becomes minimal. To determine whether a syphilis case-finding program among pregnant women is justified and affordable, the prevalence of syphilis among pregnant women should be addressed.

Example 2

Assessment of STD Syndrome Distribution and Caseload

During a two-month period, 1,500 female and 1,200 male adult attendees were counted.

Women (15 years and older) total number is 1,500

diagnosed with vaginal discharge: 160
diagnosed with genital ulceration: 20
diagnosed with lower abdominal pain: 20

Distribution of STD syndrome among women:

80% vaginal discharge
10% genital ulceration
10% lower abdominal pain

Total STD syndromes diagnosed: 200

The proportion of women having an STD syndrome over the total number of female attendees is 200 divided by 1,500 = 13 percent (for convenience, we neglect here that some women will have more than one syndrome diagnosed during the same attendance).

Other diagnosis:

malaria n = 500 (33%)
upper respiratory disease n = 220 (15%)
lower respiratory disease n = 160 (11%)
tuberculosis n= 15 (1%)
complications of pregnancy n= 100 (7%)
gastroenteritis n = 75 (5%)
skin diseases n = 100 (7%)
ear diseases n = 40 (3%)
dental diseases n = 20 (1%)
other n = 70 (5%)

This means that STDs, which account for 13 percent of the total number of attendances, are among the top three diseases for which adult women seek health care. The main diagnosis made among adult women is malaria; upper respiratory disease is second and STDs third.

Similar calculations can be made for male attendees.

Collection of Existing Data

First a search should be made for existing data on syphilis serological screening of pregnant women. Potential sources include the Ministry of Health, the Mother and Child Health (MCH) Program, and from multilateral organizations such as the United Nations International Childrens and Education Foundation (UNICEF) and the World Health Organization (WHO), nongovernmental organizations, ANC records and hospital laboratories.

Results

Data collected in this way may give information on the prevalence of reactive syphilis serology among ANC attendees. If ANC records are reviewed, it is also possible to determine the weak points in the current antenatal syphilis screening. For example, the number of tests should be the same as the number of new attendees, assuming all women are screened, and only once during preganacy. The number of treatments should be the same as the number of seroreactives identified. This sort of analysis was done in Zambia and it identified several areas in their syphilis screening program that needed to be strengthened *(see Example 3)*.

Limitations

There are some limitations to using existing data. First, it is not known how complete or unbiased the syphilis testing has been. In order to conserve test reagents, some health-care providers will only test those women they feel are at risk for syphilis. Some health-care facilities only provide syphilis screening to those women who can pay for the test.

Second, it is sometimes difficult to retrospectively determine if the testing was of good quality and adhered to high standards. If no records were kept, one cannot determine if test controls or quality reagents were used. One should suspect the test quality or a biased sample if the prevalence of reactive syphilis

Table 1

STD Drug Estimates in Zimbabwe for 1991

Syndromes	Estimated cases	Treatment cost (in US$)	Total cost (in US$)
Genital ulcer	462,270	2.91	1,345,206
Penicillin allergy	24,330	4.91	119,460
Urethral discharge	275,000	3.43	943,250
Vaginal discharge	156,510	4.23	662,037
Pregnant women with vaginal discharge	17,390	8.69	151,119
Syphilis seropos. pregnant women	10,500	0.40	4,200
Neonatal eye prophylaxis	417,800	0.04	16,712
Grand Total			3,241,984

Example 3

Syphilis screening in pregnancy, Lusaka, Zambia[8]

Expected number of pregnant women: 70,000

90 percent attendance

63,000 pregnant women attended ANC at least once. 7,000 pregnant women missed antenatal care.

46 percent were screened: 28,982 women were screened for syphilis and 41,020 missed antenatal care and syphilis screening.

10 percent seroprevalence: 2,398 women were found syphilis seroreactive. In total, 4,102 syphilis positive women missed detection.

25 percent were treated: 724 women were treated. In total, 6,276 syphilis positive women missed treatment.

serology seems too high or too low based on other information. Discussions with clinic nurses and laboratory technicians also may clarify the situation.

Prospective Data Collection

If no data are available or if the data are old or seem unreliable, a rapid survey should be started among pregnant women attending antenatal care clinics. In this group of women the proportion of pregnant women with a positive serology for syphilis may be assessed during a short period.

Study design

- **Location.** Both urban and rural locations ideally representative of the country, and with a good coverage of the area's pregnant women, should be included in the survey. A minimum of four sites should be included. In order to collect the data in a short time, the study should take place in clinics with a high attendance rate.
- **Study population.** All pregnant women attending these antenatal clinics should be included. Women reattending the clinic during the study period should not be retested as part of this survey.
- **Duration of survey and sample size.** The survey should not take longer than two to three months. During this period a minimum of 300 pregnant women per clinic should be screened. (See Example 4 for the rationale of the sample size.)
- **Data collection.** The serological tests include the *Treponema Pallidum* Haemagglutination Assay (TPHA) test, Rapid Plasma Reagin (RPR) or Venereal Disease Research Laboratory (VDRL) test *(see Chapter 12)*. Since the TPHA stays positive after effective treatment, it provides data on the proportion of women who at some time have been infected with syphilis. The RPR and VDRL tests (nontreponemal screening tests), which become negative alter treatment, provide data on the prevalence of more recent (infectious) syphilis among this population.

Data on the prevalence of treponemal antibodies should be collected by age group (two age groups: 15-24 years and older). The prevalence of a positive TPHA test (with or without positive RPR) in the younger (15-24 yrs.) age group may be regarded as the incidence of syphilis for this reason: Since sexual activity is generally uncommon before adolescence and syphilis is a sexually transmitted disease, it is reasonable to assume that TPHA seropositive women in this age group were recently infected. The prevalence of TPHA seropositive women in this age group therefore reflects the incidence (i.e., new cases) of syphilis.

The RPR and VDRL will only detect a portion of the newly acquired cases, since these tests may have become negative due to previous treatment for syphilis or the use of antibiotics for other reasons. In ages above age 24, a positive TPHA may reflect syphilis acquired in the past that already has been treated effectively. Only in a person with a previously negative TPHA test will it reflect a newly acquired case of syphilis. See Appendix 1 for an example of a surveillance sheet on syphilis screening of pregnant women.

This study will give information on the prevalence of syphilis among the general female population. The number of women with a positive TPHA over the total number of women screened gives the percentage of women who have ever been infected with syphilis. The number of women with a positive RPR over the total number of women screened gives the percentage of women with recent infectious syphilis.

As just explained, the prevalence of TPHA positive women in the age group 15 to 24 years can be regarded as the incidence of syphilis in this age group. Continuation of the screening of pregnant women for recent infectious syphilis by means of the RPR or VDRL tests, and the subsequent treatment of the seropositive women (and their partners) are an essential part of the STD program. They will have an impact on the prevalence and incidence of syphilis in the general population and on the incidence of congenital syphilis.

Example

The Relation Between Sample Size and Prevalence Estimates

Calculation of 95% confidence intervals around a prevalence estimate in ANC attenders who have syphilis serology (TPHA), where a sample of 500 was used, and 50 TPHA positive sera were identified.

The prevalence is 50/500, or 10 percent, therefore **P = 0.1.**
The sample size is 500, therefore **N = 500.**
For 95% confidence intervals (CI), **Z = 1.96**

CI = P ± Z x (P x (1 – P)/N)
95% CI = **0.1 ± 1.96 x (0.1 x (1 – 0.1)/500)**
= **0.1 ± 1.96 x 0.013**
= **0.1 ± 0.26**
= **0.074 – 0.126**
95% CI = **7.4% – 12.6%**

With 95% confidence intervals around a prevalence estimate, the calculated confidence interval is statistically likely in 95 times out of 100 to contain the hypothesized ("true") prevalence of a positive TPHA test in that population at that time.

For surveillance purposes the calculation of confidence intervals around the prevalence estimates can help to determine whether the prevalence at two different moments in time are significantly different (no overlap of the confidence interval of one estimate with a previous estimate), or whether the apparent change in the prevalence estimate is as likely due to the statistical limitations of the study (no real difference). As shown in the table, with a prevalence estimate of 10 percent, the 95 percent CI intervals are larger in smaller samples and smaller in larger sample sizes. In other words, with smaller sample sizes it may be more difficult to show differences in prevalences over time.

N Positive	Prevalence	95% CI	Prevalence	95% CI	Prevalence	95% CI
1	1.0%	0.0 – 3.0	0.2%	0.0 – 0.6	0.1%	0.0 – 0.3
5	5.0%	0.7 – 9.3	1.0%	0.1 – 1.9	0.5%	0.1 – 0.9
10	10.0%	4.1 – 14.9	2.0%	0.8 – 3.2	1.0%	0.4 – 1.6
20	20.0%	12.2 – 27.8	4.0%	2.3 – 5.7	2.0%	1.1 – 2.9
50	50.0%	40.2 – 59.8	10.0%	7.4 – 12.6	5.0%	3.6 – 6.4
100	100.0%	100 –100	20.0%	16.5 – 23.5	10.0%	8.1 – 11.9

Limitations

This survey includes the drawing of a blood sample, which the women may resist. Providing them with good information on the aim of the study may alleviate their concerns. Both the RPR and the VDRL tests can be conducted in the clinic itself, but the TPHA requires a better equipped laboratory, so storing and transportation of the samples will have to be arranged. Training of laboratory staff and quality control of the testing should also be assured prior to starting the survey. When the coverage of pregnant women by this clinic is small, the survey results will have a limited value in estimating the prevalence of syphilis among the general population of pregnant women.

Protocol 3

To determine the aetiology of syndromes and the antibiotic sensitivity of N. gonorrhoeae *and* H. ducreyi

Collection of Existing Data:

Referral centres: When there are referral centers or special STD clinics, information may be available on: (a) which clinical syndromes are most common, (b) which infectious agents are the most prevalent, and (c) what is the sensitivity of the infectious agents to available antibiotics.

Summary reports may be available in referral centres on the diagnoses. They may include etiologic diagnoses, e.g., syphilis, genital herpes, chancroid or gonorrhea. In that case it is very important to collect information on the diagnostic criteria for such a diagnosis. For example:

- When the diagnosis of gonorrhea is is given to every man with to urethral discharge, the number of gonorrhea cases may be equal to the number of cases of urethral discharge.
- When the diagnosis "syphilis" is based on genital ulceration in combination with positive syphilis serology, the diagnoses syphilis, herpes and chancroid may be combined into the syndrome "genital ulceration."

Also in case of reports on clinical syndromes one should verify the diagnostic criteria used in each facility for those syndromes. When reliable etiologic diagnoses have been made, rhe relative frequency of etiologic agents causing the syndrome should be assessed: e.g., when all patients with urethral discharge underwent a culture for gonorrhea, The proportion of the urethral discharges that are gonococcal and non-gonococcal can be determined. When cultures for gonorrhea have been taken, there may be some results on the sensitivity of the gonococcal isolates.

Prospective Data Collection:

In existing referral centers, if the sources of information on disease and infection patterns and antibiotic susceptibility of infectious agents are inadequate, the ability of reference centers, when they exist, should be strengthened to monitor (i) syndrome and organism prevalence, and (ii) antibiotic susceptibility of at least *N. gonorrhoeae (See Chapter 12).*

Study design

- **Location:** A referral clinic or STD clinic is best suited for this type of study because they are likely to have the necessary laboratory capabilities.
- **Study population:** All male and female patients attending the clinic.
- **Duration of survey and sample size:** The duration of the survey will be 2 to 3 months. The sample size will be the number of patients that visit the clinic during the study period.
- **Data collection:** The relative frequency of STD syndromes should be registered including genital ulcers (men and women), urethral discharge (men),

vaginal discharge and lower abdominal pain (women). If the patient has been treated previously for the condition for which s/he visits the clinic even if it is self treatment, this should also be recorded.

With regard to study of the etiologic agent(s) of the syndromes the following procedures are suggested.[9] Full details on procedure for obtaining adequate biological specimens are described in detail in the "Benchlevel Laboratory Manual for Sexually Transmitted Diseases" (WHO document WHO/VDT/89). Newer, more sensitive and expensive testing methodologies are rapdily becoming available such as DNA amplification techniques and ELISA based testing. These newer diagnostic methodologies could also be considered for use in this protocol if they are available. (Recommendations for the determination of the sensitivity of *N. gonorrhoeae* and recommended antibiotics can be found in Chapter 12.)

- **Specimen collection:**

  In all **genital ulcerations,** blood should be drawn by venipuncture for RPR and TPHA test, a specimens of the ulcur should be taken for culture for *H. ducreyi* and if possible for herpes simplex virus detection, and a dark field microscopic examination should take place of the exudate of the ulcur for the presence of *T. pallidum.* Tests for LGV and donovanosis will depend on whether these diseases are found in the area.

  In case of urethral discharge and/or dysuria specimens should be taken for *N. gonorrhoeae* culture and for *C. trachomatis* detection (usually antigen testing).

  In case of vaginal discharge speculum examination should take place: wet mount (saline and KOH) examination of a vaginal sample should be done microscopically for the detection of motile trichomonads, yeast cells and clue cells. Subsequently, after removal of any exocervical mucus and exudate, endocervical swab specimens should be taken for *N. gonorrhoeae* culture and for *C. trachomatis* detection.

- In case of lower abdominal pain, abdominal and vaginal examination should be performed. Subsequently, as described in vaginal discharge, wet mount examination of a vaginal sample should take place and endocervical swab specimens for *N. gonorrhoeae* culture and *C. trachomatis* detection should be collected.

See Appendix 1 for examples of surveillance sheets for the etiology of syndromes.

ANTIBIOTIC SENSITIVITY TESTING:

More details on antibiotic susceptibility testing can be found in Chapter 12. The number of strains to be examined must be large enough to permit valid inferences about the population from which the sample was taken. The proportion of resistant strains in the sample should be precise; in other words, the sample estimate must be close to the true proportion of resistant strains in the population under investigation.

Data from a referral site most probably provide the "worst case scenario" with regard to antimicrobial sensitivity as people come or have been referred to the clinic because of failure of previous treatment. For this reason information should be collected whether one has been treated previously or not.

Alternatively, one should try to assess the etiology of syndromes and the microbial resistance in an OPD of a health facility with a well equipped laboratory or within easy reach of a laboratory. This may be an OPD in the public health sector or in the private sector.

As in many areas individual etiologic diagnosis of STD is not possible, treatment guidelines will be based on the diagnosis of syndromes. However, on the basis of the relative frequency of different pathogens causing the syndromes and their susceptibility to (available) drugs, national guidelines for STD case management can be established.

Repetition of this survey on the etiology and sensitivity of the drugs after a certain period (one to two years) will be needed to determine whether the treatment guidelines are still appropriate or whether they should be modified.

Limitations: This survey can only take place in a clinic with a well equipped laboratory nearby. Before starting the survey, health staff must be properly trained how to examine the patients, how to diagnose the syndromes, and on the proper collection of the samples. Additionally, the laboratory methods and quality assurance as well as the training of the laboratory technicians for the proposed tests should be assessed.

Protocol 4

To determine the prevalence of gonorrhea, chlamydial infection and trichomoniasis in women attending health facilities, but not seeking STD care

PROSPECTIVE DATA COLLECTION:

Most women with STD are asymptomatic, and therefore do not seek health care. To estimate the prevalence of STD in women not seeking STD care, one may study women attending antenatal clinics. This population, as mentioned above, is often fairly representative of the general population of women.

Study design:

- **Location:** The study should take place in both an urban and a rural clinic. The clinics chosen, should have a good coverage of the population of pregnant women. In order to conduct this survey during a short period, the survey should take place in clinics with a high attendance rate (see also duration of survey and sample size). The same antenatal clinics may be included that were chosen for the survey on the proportion of pregnant women with a reactive syphilis serology.
- **Study population:** All pregnant women attending the clinic during the study period. Women reattending the clinic will not be retested as part of this survey.
- **Duration of survey and sample size:** The duration of the survey should not take longer than 2 to 3 months. The sample size will be the total number of different women attending the clinic during the survey. During this period a minimum of 500 pregnant women per clinic should have been screened. (See Protocol 2 for rationale of the sample size.)
- **Data collection:** Data should be collected by age group. In addition information should be collected whether a woman has complaints of genital ulceration, vaginal discharge or lower abdominal pain. Speculum examination should take place: wet mount (saline) examination of a vaginal sample for microscopical detection of motile trichomonads. After removal of any exocervical mucus and exudate, endocervical swab specimens should be collected for *N. gonorrhoeae* culture and *C. trachomatis* detection.

Since these women are not seeking STD health care, results of this study will give information on the prevalence of these STD in the general sexually active female population. However, the prevalence may be an underestimate as women who are infertile do not attend the antenatal clinic (the infertility will be for a large part due to STD in the past and part of these women may still be at increased risk for STD. In case of a high prevalence of STD and if affordable, a case finding program among these women (including treatment of infected persons) may be justified as part of the national STD program. This survey can only take

Example 5

STD PREVALENCE SURVEY OF PREGNANT WOMEN AND PROSTITUTES IN KINSHASA, ZAIRE[10]

Finding	No. (%) with finding in indicated group: Pregnant women (n=1,160)	Prostitutes (n=1,222)
Antibody to HIV	56 (4.8)	433 (35.4)
Positive syphilis serology (RPR & TPHA both positive)	13 (1.1)	193 (15.8)
N. gonorrhoeae	19 (1.6)	286 (23.4)
C. trachomatis	60 (5.2)	159 (13.0)
N. gonorrhoeae and/or *C. trachomatis*	75 (6.5)	379 (31.0)
T. vaginalis	213 (18.4)	267 (21.8)
Genital ulcer	1 (0.1)	66 (5.4)

place in a clinic with a well equipped laboratory nearby. Before starting the survey, the health staff ust be properly trained in speculum examination, microscopic examination of wet mounts and proper collection of samples.

The STD prevalence determined by the survey may be an underestimate for the reasons described above.

Protocol 5

To determine the prevalence of STD in high risk groups who do not seek health care

The first hurdle in this survey is to identify populations at high risk for contracting STD. Data on populations at risk for HIV (and therefore other STD) may already be available through the AIDS program, which may have conducted studies that have identified these populations at risk. If no high risk populations have been identified, do so first. Subsequently, assess the relative importance of the identified high risk populations in the transmission of STD *(See Chapter 13)*. Examples of high risk populations are male truck drivers and CSWs.

Prospective data collection: STUDY DESIGN:

For a more detailed explanation see also the methods for syphilis screening and the survey to assess the prevalence of gonorrhea, chlamydial infection and trichomoniasis among pregnant women.

- **Location:** Populations at high risk for STD may only be seen in public health-care facilities when they are symptomatic or for legal reasons. But even, being symptomatic, they may decide not to go to public health-care facilities for fear of stimatization. Therefore, in order to assess the prevalence of STD among various (asymptomatic and symptomatic) high risk populations, look for them outside the health facilities and bring them into a clinic, which may be a clinic established for the purpose of this study only (e.g., a mobile clinic) or into an existing health facility.
- **Study population:** Identified high risk groups (see above) might br chosen based on importance in STD epidemiology or because of access to the population.
- **Duration of the survey and sample size:** The sample size of a high risk population depends on the estimated prevalence of the STD in that population. In general, assume that the prevalence of the various STDs is much higher in, for example, CSWs than in pregnant women and therefore the sample size may be smaller. The data on STD prevalence in pregnant women and CSWs, Kinshasa, Zaire, illustrate this point *(see Example 5)*. Preferably, the duration of the survey should not be longer than two to three months.
- **Data collection:** Minimally, one should collect serum samples for syphilis screening (TPHA and RPR/VDRL). In addition, one should try to screen for *N. gonorrhoea, C. trachomatis,* trichomoniasis (women only) and for the presence of genital ulcerations.

Results:

In case of a high prevalence of STD a special STD program for these high risk populations may be justified as part of the national STD program *(see Chapter 13)*. As such a survey can only take place on a voluntary basis, the STD prevalence may be an underestimate or overestimate, depending on the risk behavior of the participants compared to the mean risk behavior of the population under investigation.

Of special note, when one starts special surveys among populations at risk, combine STD assessment with treatment (preferably free of charge) of the infected cases. Persons from the high risk groups may then also be more inclined to participate in such a survey.

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