
Planning Appropriate Cervical Cancer Control Programs

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Program for Appropriate Technology in Health (PATH)

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PATH welcomes comments on this document, including suggestions for improvements and readers' experience in using the document to educate providers, policy makers, and others. Please send your comments to Jacqueline Sherris at PATH (E-mail: sherris@path.org).

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Summary of Key Recommendations

During the past decade, much has been written about the challenges involved in controlling cervical cancer in low-resource settings and strategies that are likely to be most effective in these settings. This document summarizes various research, program experience, and analyses related to cervical cancer control, with a focus on program and policy implications. The document presents numerous suggestions for program managers and policy makers to consider as they design cervical cancer control programs. Overall, programs must plan to achieve the minimum program goals listed below to have an impact on cervical cancer incidence and mortality:

- ❖ Increase awareness of cervical cancer and preventive health seeking behavior among women aged 35 to 50 (a reasonable target age group for a new cervical cancer control program with limited resources).
- ❖ Screen all women aged 35 to 50 at least once before expanding services to other age groups or decreasing the interval between screening.
- ❖ Treat women with high-grade dysplasia, refer those with invasive disease where possible, and provide palliative care for women with advanced cancer.
- ❖ Collect service delivery statistics that will facilitate ongoing monitoring and evaluation of program activities and outputs.

As a new or expanded program is designed, it is crucial to ensure strong management and support for program strategies at all levels of the health care system. Gaining this support can be made easier by clearly demonstrating the need and demand for a cervical cancer control program. Analyses of the estimated costs and impact of suggested program approaches also are important. Another important part of program planning is to involve potential providers and clients in program design to ensure that their perspectives are considered and their needs are met.

Activities that are key to achieving minimum program goals in many low-resource settings include:

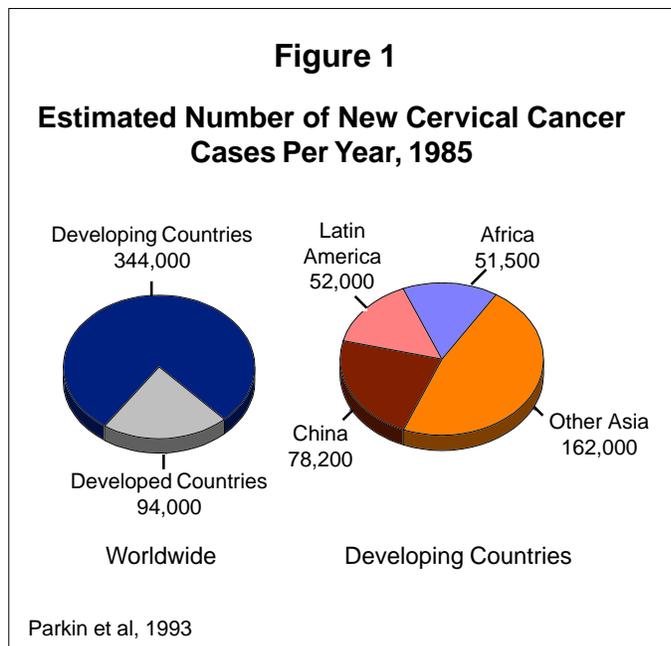
- Coordinating cervical cancer control services with health programs that offer related services and/or reach older women.
- Identifying and addressing bottlenecks to effective service delivery (for example inadequate cytology services or inadequate information systems) before initiating a new program.
- Removing regulatory barriers to broadening access to services, such as regulations that do not allow nurses to provide Pap smears.
- Ensuring that providers at all levels are trained in appropriate cervical cancer control care, including counseling skills.
- Using innovative, culturally appropriate, field-tested strategies to reach out to underserved older women.
- Supporting targeted research on new screening and treatment approaches that may increase access to services and cut program costs.

Through creative service delivery strategies and well-trained, dedicated staff, new cervical cancer control programs can address the challenges of providing appropriate screening and treatment and ultimately have a lasting effect on women's health.

Cervical Cancer: Magnitude of the Problem

As one of the most common cancers in developing countries, cervical cancer has had a devastating impact on women throughout the world. Data from the mid-1980s suggest that the disease is the third most common cancer (after lung and stomach cancers) and is the leading cause of death from cancer among women in developing countries (Parkin et al, 1993). About 350,000 new cases are identified in developing countries each year, where screening programs are not well established or are minimal, compared with fewer than 100,000 in developed countries, where secondary prevention efforts generally are well established (see Figure 1). The figure from developing countries is almost surely an underestimate because of the shortage of medical providers and underdeveloped medical information systems in many regions.

The highest age-standardized incidence of cervical cancer in a 1985 worldwide study of cancer incidence was reported in eastern and southern Africa, where the rates were over 45 per 100,000 women. Rates of 20 per 100,000 women or more were reported from much of the developing world, with the notable exception of China and the countries of the Middle East, Western Asia, and North Africa (see Figure 2).



An important reason for the sharply higher cervical cancer incidence in developing countries is the lack of effective screening programs aimed at detecting precancerous conditions and treating them before they progress to invasive cancer. It has been estimated that only about 5 percent of women in developing countries have been screened for cervical neoplasia in the past 5 years compared with some 40 to 50 percent of women in developed countries. This lack of access to screening compounds the high levels of other risk factors, particularly human papilloma virus (HPV) infection, among women in many parts of the developing world.

Prevalence

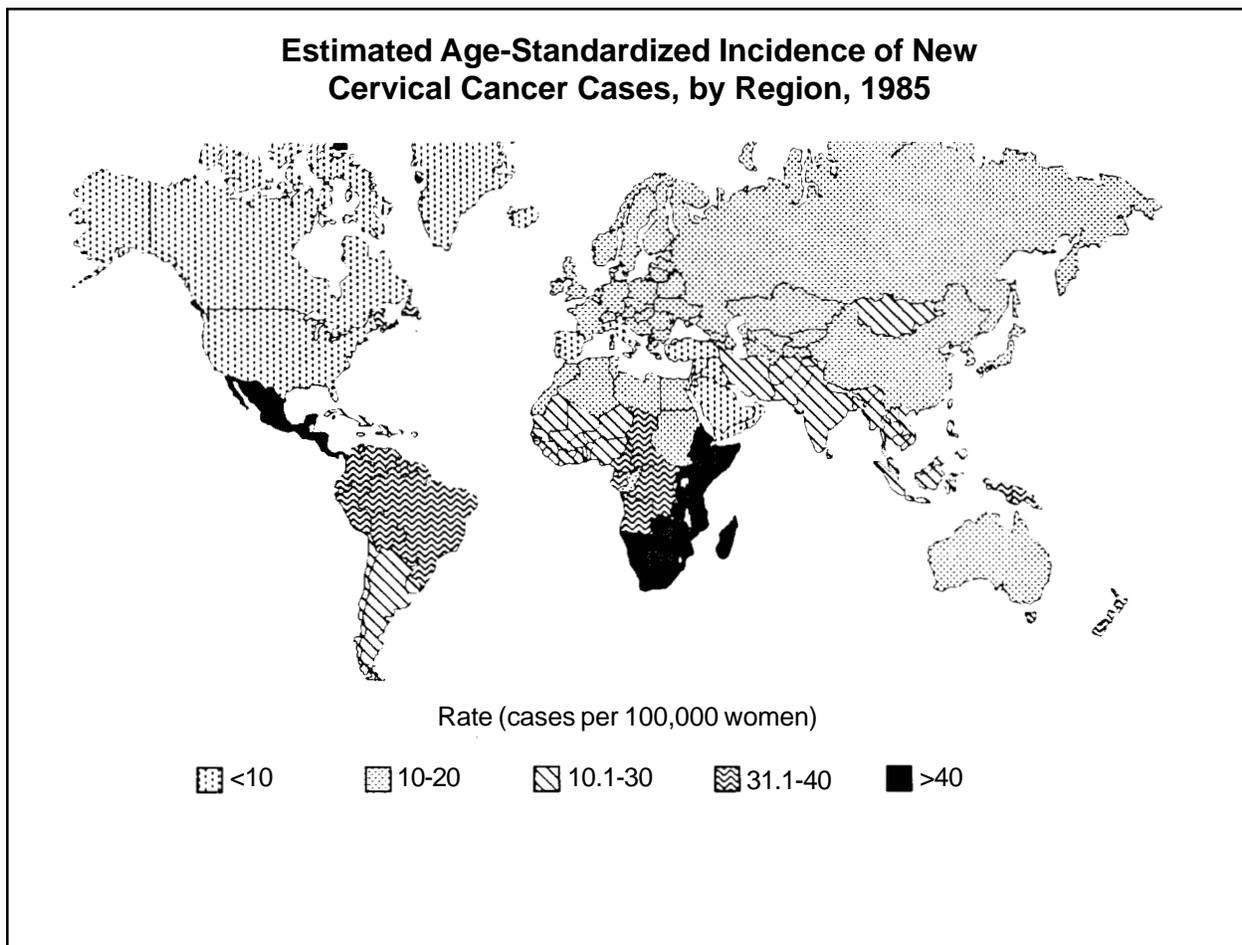
Data suggest that in 1985 there were over 2.3 million prevalent cases of clinically recognized cervical cancer worldwide: about 0.6 million in developed countries and 1.7 million in developing countries. These estimates reflect the accumulation of cases each year and the fact that few women in developing countries receive treatment. Current (1996) prevalence is likely about 2.5 million. Current knowledge of the natural history of cervical cancer suggests that two to five times as many women may have potential precursors to cervical cancer as have invasive cancer.

Mortality

The levels of mortality associated with cervical cancer are the most telling indicator of its impact on women, their families, and their communities. Mortality data occasionally are used as substitutes for incidence data in countries with little screening or treatment activity, since cervical cancer is nearly always fatal if not detected and treated. Based on 1985 data on identified cases, a very conservative estimate of deaths worldwide each year due to cervical cancer is about 200,000, with most of these deaths occurring in developing areas. A 1986 analysis suggested that by the year 2000, worldwide about 550,000 person-years of life would be lost from cervical cancer each year if effective screening programs are not initiated.

Age Distribution

Age-specific incidence generally peaks at about 100 per 100,000 women in women aged 40 to 50. Age-specific rates generally are low in women in their 20s and early 30s; data from cancer registries in developing countries indicate that approximately 80-90 percent of confirmed cases were among women aged 35 or older. There are few regional differences in the pattern of age-specific incidence rates. Differences in the proportion of cervical cancer cases in different age groups likely reflect the underlying age structure of the population or possibly the fact that older women simply are not being screened. This would account for the lower average age of women with the disease reported in some developing countries.



Key references in the preparation of this section were Parkin et al, 1993; WHO, 1985; and Eddy, 1986 (see Bibliography).

Introduction: Fact Sheets

The following seven fact sheets summarize key information related to the provision of cervical cancer control services. They address the natural history of cervical cancer, screening approaches and technologies, treatment approaches and technologies, follow-up strategies, palliative care, program monitoring and evaluation, and information needs. Each fact sheet begins with a review of issues and research related to the topic, and then describes feasible approaches in low-resource settings and policy implications. Only key references are listed for each fact sheet; brief summaries of these references and other important documents are included in the bibliography. The fact sheets can “stand alone” or be used as a packet. They may be reproduced and used without permission.

Natural History of Cervical Cancer

A clear understanding of the natural history of cervical cancer is key to planning and implementing a rational, cost-effective cervical cancer control program. Accepted models of cervical cancer natural history have changed in recent years. Because the natural history of the disease has a direct impact on screening, treatment, and follow-up strategies, programs should base their decisions on the most current models.

When cervical cancer control programs first were developed, it generally was assumed that cervical cancer developed from precursor lesions (broadly known as dysplasia), progressing steadily from mild to moderate to severe dysplasia to carcinoma *in situ* (CIS) before cancer develops. In fact, it now appears that the direct precursor to cervical cancer is high-grade dysplasia, which can progress to cervical cancer over a period of up to 10 years. Most lower-grade dysplasia regresses or does not progress, particularly lower-grade incident cases in younger women (aged 34 or less). Prevalent cases are less likely to regress.

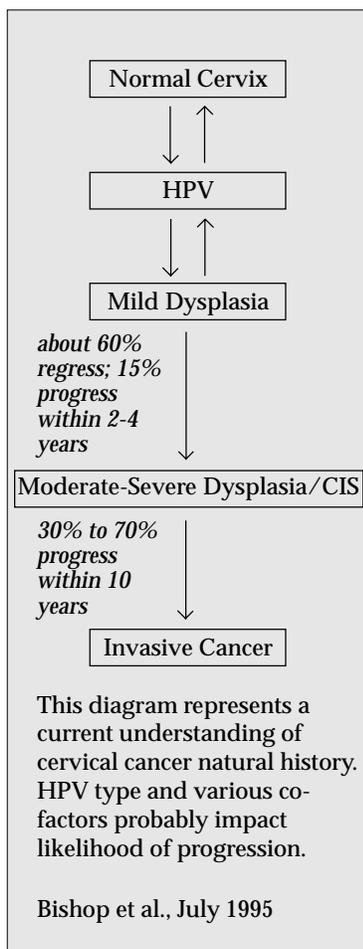
The primary underlying cause of cervical cancer is human papilloma virus (HPV), a sexually transmitted infection; certain types of HPV are more strongly associated with cancer than others. Other factors that may influence whether a woman with dysplasia is likely to develop cervical cancer include tobacco use, nutritional status, and some hormonal factors, such as early age at first birth and use of some hormonal contraceptives. Most other factors identified as associated with cervical cancer—for example, age at first intercourse and number of sexual partners—are most likely indicators of risk of HPV exposure rather than independent risk factors.

Key Considerations for Low-Resource Settings

It is important to take into account the current understanding of the natural history of cervical cancer in deciding:

- ❖ when to initiate screening,
- ❖ how often to screen, and
- ❖ when to recommend treatment and/or follow-up.

The natural history of cervical cancer suggests that screening should initially focus on women at the highest risk of high-grade dysplasia—women in their 30s and 40s. Cervical cancer most often develops in women after age 40, and high-grade dysplasia generally is detectable up to 10 years before cancer develops, with a peak dysplasia rate at about age 35. Unscreened women over 50 remain at relatively high risk of cervical cancer, though women in this age group who have had one or more negative screens in their 30s or 40s are at lower risk. The benefit of screening post-menopausal women may be reduced by lower sensitivity of Pap screening due to changes in vaginal tissue and cervical anatomy.



In a few countries, data suggest that age-specific rates have shifted downward by five years, and screening recommendations for those countries need to be adjusted accordingly. Generally, though, observation of more cases in younger women reflects a population's age structure or screening patterns rather than a shift in age-specific rates.

Both natural history models and clinical data suggest that cervical cancer generally develops slowly from precursor lesions. Therefore, screening can take place relatively infrequently and still have a significant impact on morbidity and mortality. Screening every three years has almost as great an impact as screening every year. Even screening every 10 years can have a significant impact. Screening emphasis, then, should be on coverage rather than on frequency.

Where resources are scarce, current understanding of cervical cancer natural history strongly suggests treatment of cervical lesions should focus on high-grade dysplasia, with follow-up mechanisms in place for women with lower-grade lesions. From 30 to 70 percent of untreated high-grade dysplasia will progress within 10 years whereas most low-grade dysplasia regresses spontaneously or does not progress.

Policy Implications

As part of efforts to offer services that will have the greatest impact on cervical cancer incidence and mortality, programs should consider the following issues:

- ❖ Ensure that screening efforts initially focus on women at highest risk of cervical cancer precursors (women age 35 to 50 is a reasonable starting point) and that treatment is focused on women with high-grade dysplasia. As programs mature, screening should gradually be expanded to women aged 30 to 60.
- ❖ Disseminate summary information and key research papers on cervical cancer natural history to the medical establishment and providers so that they understand the rationale for screening and treatment recommendations.
- ❖ Ensure that reliable follow-up and tracking procedures are in place and functioning so women identified with low-grade dysplasia can be screened more frequently than the population as a whole, and that data on the proportion of women who develop more serious cervical abnormalities can be monitored.
- ❖ Support targeted research on accurate, inexpensive HPV tests since, ultimately, HPV testing could be an important addition to targeted screening programs and could help guide treatment decisions.

Key references in the preparation of this fact sheet were Nasiell et al, 1986; Ponten et al, 1995; and Richart, 1995.

The natural history of cervical cancer suggests that screening should focus on women at the highest risk of high-grade dysplasia—women in their 30s and 40s—and that screening can take place relatively infrequently and still have a significant impact.

Screening Approaches and Technologies

Cervical cancer screening programs continue to be redesigned in many countries, generally reducing the frequency among women who have had at least one normal smear and recommending regular follow-up rather than treatment for women with mildly abnormal smears.

Reduction in Cumulative Cervical Cancer Rate with Different Frequencies of Screening

Frequency of screening*	% reduction in cumulative rate
1 year	93.5
2 years	92.5
3 years	90.8
5 years	83.6
10 years	64.1

* Screening all women age 35-64 who have had at least one previous negative screen

IARC, 1986

Cervical cancer prevention efforts worldwide have focused on screening women at risk of the disease using Pap smears and treating precancerous lesions. Where screening quality and coverage have been high, these efforts have reduced invasive cervical cancer incidence and mortality by as much as 90 percent.

Pap smears involve scraping cells from the cervix, fixing and staining them on a glass slide, and having them evaluated by a trained cytologist. In most developed countries, women are advised to have their first Pap smear soon after becoming sexually active and subsequently every one to three years; many national guidelines are moving to less frequent rather than more frequent Pap smears. Women with mild dysplasia generally are advised to return for routine follow-up smears. High-grade lesions, including carcinoma *in situ* (localized cancerous lesions) generally are further evaluated via colposcopy (examination of the cervix with a special microscope) and biopsy of suspicious areas.

While Pap smear-based screening efforts have been introduced in many developing countries, in general they have achieved limited success. Some of the problems these programs have faced include: screening tends to be offered only opportunistically (often on a fee basis) to younger, relatively low-risk women; cytology services are limited and often face quality-control challenges; follow-up diagnostic and treatment services are unavailable to most women; and at-risk women tend to be unaware that cervical cancer is a preventable condition and that having a Pap smear plays an important role in prevention.

Feasible Approaches for Low-Resource Settings

Can successful, cost-effective cervical cancer screening programs be implemented in low resource settings? Key to program success are:

- ❖ Ensuring that screening tests are as accurate as possible.
- ❖ Initially limiting screening efforts to women at highest risk of high-grade dysplasia, generally those aged 35 to 50, since cervical cancer is rare in younger women.
- ❖ After one normal Pap smear, screening relatively infrequently (every 3, 5, or even 10 years where resources are very limited).
- ❖ Treating only women with moderate to severe dysplasia since mild dysplasia generally regresses spontaneously.
- ❖ Using outpatient diagnostic and treatment approaches (such as cryotherapy and loop electrosurgical excision), which are less costly, time-consuming, and uncomfortable than

traditional approaches (such as cone biopsy or hysterectomy).

Alternative approaches to cervical cancer screening include visual screening to identify cervical lesions without reliance on cytology, human papilloma virus (HPV) tests that may be able to identify women at high risk for cervical cancer, and automated Pap screening machines to identify subsets of Pap smears that should be examined by cytologists. Studies are ongoing in many areas to evaluate these and other approaches to cervical cancer control; they are being evaluated for clinical effectiveness, acceptability to clients and providers, and cost-effectiveness. In the short run, until research results are available, country programs will need to continue to focus on improving access to Pap smears. At the same time, targeted research or new approaches that may ultimately increase access to screening in low-resource settings should be encouraged.

Policy Implications

As part of efforts to offer services that will have the greatest impact on cervical cancer morbidity and mortality, screening programs should consider the following issues:

- ❖ Ensure a public health approach to cervical cancer control, including:
 - Determining appropriate screening strategies aimed at high-risk women.
 - Working with influential medical groups to ensure that all providers understand and support a public health approach to cervical cancer control.
 - Working with medical, nursing, and midwifery schools to ensure a public health approach is included in their curricula.
- ❖ Ensure access to needed services, including:
 - Only initiating screening when adequate diagnostic and dysplasia treatment services are readily accessible to women who need them.
 - Ensuring adequate training/education for providers in screening and follow-up strategies.
 - Broadening provider guidelines to ensure that nurses and other non-physicians can offer Pap smears and other key screening or treatment interventions.
- ❖ Support targeted operations research and new screening and diagnostic approaches as part of efforts to increase cost-effective access to cervical cancer screening services.

Key references in the preparation of this fact sheet were Sherris et al, 1993 and Richart, 1995.

New Screening Approaches

In the next several years, new approaches to screening women at risk of cervical cancer will likely become more widely available. These include visual screening to identify cervical lesions without reliance on cytology, HPV tests to identify women at high risk for cervical cancer, and automated Pap screening machines to identify subsets of Pap smears that should be examined by cytologists. All of these approaches are currently being examined and face various challenges related to clinical protocols, sensitivity/specificity, and cost. Many researchers believe that, in the long run, development of an effective HPV vaccine could largely eliminate cervical cancer as a disease threat, and therefore the need for extensive screening programs.

Programs that aim to screen the highest-risk women can have a significant impact on the rate of cervical cancer at a much lower cost compared with programs that aim to screen all women of reproductive age and provide follow-up to all women with abnormal screening results.

Treatment Approaches and Technologies

Treating precancerous cervical lesions is far more successful and cost-effective than treating cervical cancer.

Treatment Options for Dysplasia/Carcinoma in situ

	Cryotherapy	Loop Electrosurgical
Effectiveness	80%-90%	90%-95%
Side Effects	watery discharge, risk of infection	bleeding
Anesthesia Required	no	yes
Tissue Sample	no	yes
Power Required	no	yes
Cost	relatively low	relatively high

Bishop et al., July 1995

In most industrialized countries, management of preinvasive cervical conditions has shifted from use of inpatient methods such as cone biopsy and hysterectomy toward use of conservative, outpatient approaches. Although appropriate for certain circumstances, inpatient approaches are expensive and often result in over-treatment of women. In addition, they can be associated with serious complications and side effects and require significant resources for anesthesia, equipment, and inpatient care.

Appropriate Treatment Technologies

Relatively simple, outpatient procedures may be used to destroy or remove precancerous tissue. The specific treatment used depends on the severity, size, and location of the lesion.

Ablative methods, which destroy abnormal tissue, include cryotherapy, cold coagulation, laser vaporization, and electrosurgery (cauterization). Of these, cryotherapy, which freezes abnormal cells, may be most practical for low-resource settings because of its simplicity and low cost. It is generally most effective in treating moderate-grade lesions.

The main outpatient *excisional method* is loop electrosurgical excision procedure (LEEP), also known as large loop excision of the transformation zone (LLETZ). LEEP removes the entire transformation zone, providing a tissue sample for analysis, which sharply reduces the possibility of overlooking invasive cancer. At a minimum, LEEP services could be available at central referral sites, while cryotherapy could be more widely available in peripheral settings. Other basic equipment required for treatment includes surgical tables, specula, a light source, sterilization equipment, and antibiotics.

Some programs have begun to adopt a “See and Treat” approach to treating preinvasive lesions, in which LEEP is used to remove tissue for diagnosis and treatment immediately following diagnostic examination. This approach avoids the delay of waiting for diagnostic biopsy results before treatment and reduces the number of visits a woman must make to receive proper care. It may result in some overtreatment, however.

All outpatient treatment methods traditionally have required colposcopy (which uses a special magnifying scope) to visualize the cervix for pretreatment assessment, to guide diagnostic biopsies, and, in most cases, to facilitate the treatment procedure. Colposcopes, however, are very expensive, require substantial training to use, and are not readily available in many developing countries. Identifying and validating alternatives to colposcopy, such as a portable magnifying device, may significantly facilitate

management of pre-cancerous conditions in low-resource settings.

Appropriate Treatment Protocols

As knowledge regarding the natural history of cervical cancer, including the role of human papilloma virus, has increased, the most common treatment strategy in most industrialized countries is to treat only high-grade dysplasia since low-grade conditions are likely to regress. Individual country strategies, however, will depend on assessments of local capability to treat or monitor women, on local epidemiology, and on cost factors.

Treatment of Invasive Cancer

At a minimum, cervical cancer control programs must have some surgical treatment available (cone biopsy, hysterectomy) for cases of early cancer. In addition, for women with untreatable conditions, palliative care must be available (see Fact Sheet on Palliative Care).

Policy Implications

Cervical cancer control programs should consider the following issues regarding treatment:

- ❖ Rely on outpatient treatment technologies as much as possible.
- ❖ Expand access to treatment services by:
 - making cryotherapy available at the local level, while ensuring that cryotherapy and/or LEEP is available at central or regional referral centers.
 - broadening provider guidelines to support the training of non-physicians to perform outpatient treatment such as cryotherapy.
- ❖ Treat only high-grade or only severe lesions instead of all dysplasia, since most low-grade dysplasias regress spontaneously.
- ❖ Support research to explore alternative protocols (such as the “See and Treat” approach) and technologies (such as hand-held magnifying devices to visualize the cervix) so that the number of visits required for screening, diagnosis, treatment, and follow-up may be reduced.
- ❖ Offer palliative care at the primary health care level (see 2-9 for more details).

Some programs have begun to adopt a “See and Treat” approach to treating preinvasive lesions, for which LEEP is used to remove tissue for diagnosis and treatment immediately following diagnostic examination.

Key references in the preparation of this fact sheet were Andersen and Husth, 1992; Bishop et al., July 1995; Keijser et al, 1992; and Richart and Wright, 1993.

Follow-Up Strategies

Key to the success of any cervical cancer control program is the establishment of appropriate follow-up strategies linking screening, diagnosis, treatment, and monitoring of women with low-grade or treated conditions.

Many reproductive health programs may be able to provide routine treatment for precancerous lesions (using simple approaches such as cryotherapy and LEEP). Care for more serious conditions requires other strategies. With appropriate planning and policy guidance, provincial or tertiary care facilities should be able to provide diagnosis and treatment of advanced and difficult cases, while minimizing their role in screening.

Well-functioning information systems are essential to successful client follow-up, as well as to program monitoring and evaluation, quality assurance, and identifying at-risk women.

Conventional approaches to cervical dysplasia management require one or more visits each for screening, diagnosis, treatment, and follow-up. In developing countries, however, such rigorous follow-up protocols may be impossible due to transportation difficulties, long delays between diagnosis and treatment, lack of appropriate referral sites, and poor communication between clinics, laboratories, and clients. In addition, some clients may not return for follow-up visits because they do not understand the necessity of further evaluation, they are afraid of receiving bad news about their condition, or they fear treatment or other procedures.

Key Considerations

Integrating Services. Integrating cervical cancer control and prevention with other primary health care services helps improve follow-up. Existing programs such as maternal/child health, sexually transmitted disease, sterilization, tuberculosis (TB), hypertension, or other outpatient services often have some capability to provide cervical cancer screening and to ensure appropriate follow-up. This includes procuring and transporting diagnostic tests and supplies; communicating between clinics and laboratories; and developing counseling, follow-up, and record-keeping systems. Monitoring women who have been diagnosed with low-grade dysplasia or who have undergone treatment for severe dysplasia is another important aspect of cervical cancer prevention that can be provided through integrated services.

Experience in some countries, such as Latin America, however, has indicated that integrating services can be difficult due to competing priorities and understaffed clinics. An alternative approach has been to have follow-up and program monitoring activities taking place at a secondary level, such as in adult health clinics.

Information Systems. Client records should allow programs to follow individual women over time, and they should include a client's screening results, diagnostic referrals, and treatment outcomes. These records should be set up so that women can be recalled for screening at appropriate intervals or for repeat screening, diagnosis, and treatment due to abnormal screening results. To do this, a simple registry of the population being served could be established using a basic card system. Cards should include the woman's name, an identification number, address, date of birth, family contact, date of each screening test, the results, and any treatment referral details. Pathology reports should be filed with the client's card. Women also could be given a screening record card (with identification numbers linked to

clinic records), detailing their screening visits and results to help remind them of when they must return and to inform new providers of their screening history if they move. Ideally, information from client records should be linked to regional or national databases to allow easy aggregation of data on key evaluation indicators. If such a system is not feasible, using sentinel surveillance methods for data collection and monitoring could be a practical alternative.

Reducing the Number of Clinic Visits. In many low-resource settings, especially in rural areas, women's access to health services may be limited because of distance from clinics, transportation costs, and family or work responsibilities. Reducing the number of clinic visits for screening and treatment, therefore, may make it easier for women to receive the care they need. One method that has been studied is the "See and Treat" approach, which eliminates the need for women to wait for the results of directed biopsy before returning for treatment. (See the Treatment Approaches and Technologies Fact Sheet for more information on this approach.)

Educating Women. Qualitative research in several countries indicates that not only are many women not aware that early diagnosis and treatment of cervical dysplasia can prevent cervical cancer, but they also may not understand the importance of returning for follow-up (either for diagnosis, treatment, or repeat screening) when their screening results are abnormal. Therefore, counseling and education are essential to ensure that women who need additional services get them.

Policy Implications

To address the challenges of developing feasible follow-up strategies, the following policy initiatives might be considered:

- ❖ Support integration of cervical cancer screening and treatment into existing reproductive health programs, where feasible.
- ❖ Endorse research to explore alternative screening and treatment approaches that may reduce the number of clinic visits required.
- ❖ Establish adequate information systems with linkages to regional or national databases to ensure that women are followed up appropriately.
- ❖ Ensure that women receive adequate information and counseling about their conditions, the need to return for follow-up, and what they will experience at each stage of intervention (screening, diagnosis, and treatment).

Key references in the preparation of this fact sheet were Miller, 1992 and PAHO, 1990.

In Colombia, women are given record cards that include Pap smear dates, results, and suggested follow-up.

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<i>Lo moderno es curarse en salud</i>

Palliative Care for Advanced Cervical Cancer

Palliative care:

- affirms life and regards dying as a normal process
- neither hastens nor postpones death
- provides relief from pain and other distressing symptoms
- addresses the psychological and spiritual needs of patients
- offers a support system to help patients live as actively as possible until death
- offers a support system to help families cope with the patient's illness and their bereavement

WHO, 1990

Any cancer control program has to address the needs of patients with advanced cancer. For cervical cancer control programs, there always will be women whose disease was not identified early; for new programs, this can be a particular challenge since widespread screening will uncover previously unidentified cases. For programs working with limited resources, it is seldom possible to provide the staff, equipment, and facilities necessary to treat invasive cancer; therefore, efforts must focus on ensuring that palliative care is available to women with advanced, terminal disease.

Palliative care is the active, total care of patients whose disease is not responsive to curative treatment (or for whom curative treatment is not available). Control of pain, of other symptoms, and of psychological, social, and spiritual problems are all part of palliative care: the overall goal is to achieve the best possible quality of life for patients and their families.

While most would agree that compassionate care should be provided to gravely ill women, in many areas there are major barriers to providing palliative care. These include the absence of national health policies on cancer pain relief and other aspects of palliative care; lack of training of health care providers and policy makers in the principles of palliative care; and restrictions on drugs demonstrated to be effective in controlling severe pain, often because of concern about the legality of certain opioid drugs that also are classified as narcotics.

Some of the specific concerns that have resulted in restriction of opioid drugs may be unfounded. For example, data suggest that medical use of opioids is rarely associated with psychological dependence on the drugs. There also is little evidence to support the concerns that cancer patients develop "tolerance" to opioids. In fact, dosages generally are increased because pain tends to increase as the disease progresses. Lastly, concerns about diversion of drugs for illicit use can be addressed by national drug guidelines that mandate specific uses and distribution requirements. Nevertheless, international narcotic regulations have resulted in shortages and/or prohibitive pricing of opiates in some regions.

Feasible Approaches in Low-Resource Settings

In many regions, one of the first steps that must be taken to providing palliative care is ensuring that providers discuss a cervical cancer diagnosis and its implications with their patients and/or patients' families. It generally is difficult for nurses and physicians without special training to discuss the prognosis of

grave disease and death: as a result, a cervical cancer diagnosis often is discussed quickly and superficially, if at all.

Beyond training in how to talk with patients and their families about cancer and death, providers need training in managing pain, addressing other symptoms of the disease, and providing counseling support to patients and their families. As this training is put in place, programs must ensure that the drugs proven to be effective in controlling cancer pain, including the opioids morphine and codeine, are available.

An important step to increasing access to palliative care in low-resource settings is recognizing that the vast majority of women with terminal cervical cancer will be cared for at home. Therefore, it generally makes sense to establish systems and mechanisms to support the families providing the care, rather than to expend resources on hospital-based care or special hospices, which generally are available to only a minority of those in need.

Policy Implications

To ensure that women with advanced cervical cancer have access to effective, compassionate palliative care, cervical cancer control programs, in conjunction with broader cancer programs, should address the following issues:

- ❖ Disseminate information about appropriate palliative care to policy makers and providers at all levels.
- ❖ Train providers in the principles of palliative care, including the medical uses of opioid drugs.
- ❖ Evaluate drug regulations and medical/pharmaceutical policies that may unnecessarily restrict access to appropriate drugs, including opioids.
- ❖ Train providers in interpersonal communication and counseling skills to help them discuss cancer and death with patients and their families.
- ❖ Assess and implement strategies to provide support for families providing palliative care in the home, including teaching family members to administer necessary drugs.

In 1992, the Costa Rican Supreme Court declared that every Costa Rican has the right to die with dignity and with no pain. This decision was prompted by the plight of a terminally ill cervical cancer patient who was unable to obtain sufficient pain control medication because of established policies of hospital-based pharmacists.

Key references in the preparation of this fact sheet were WHO, 1990 and WHO, 1996.

Program Monitoring and Evaluation

Monitoring and evaluation of a cervical cancer control program's operations and impact are essential to determining whether the program is meeting its objectives effectively and efficiently.

To ensure maximum impact, evaluation results should be reported to appropriate program personnel along with recommendations for corrective action, if needed.

Monitoring and evaluation of a cervical cancer control program's operations and impact are essential to determining whether the program is meeting its objectives effectively and efficiently. Results of program monitoring and evaluation can be used to help ensure appropriate delivery of services and to correct problems in program operations. Positive evaluation results also can be used to mobilize continued financial and political support for the program.

Because some aspects of evaluation can be time-consuming and costly, it is important that cervical cancer control programs establish monitoring and evaluation strategies that are feasible given the program's technical and financial resources. Whenever possible, these strategies, along with mechanisms for quickly relaying evaluation data between program sites, should be in place at the start of program activities.

Feasible Approaches in Low-Resource Settings

Ideally, evaluation of a cervical cancer control program should address both ongoing activities (for instance, how well the program's screening and treatment services are functioning and whether women with untreatable disease are receiving palliative care) and long-term impact (for instance, whether the program has helped reduce cervical cancer incidence rates). Because evaluating program activities (process indicators) generally is faster, easier, and less costly than evaluating long-term impact, it should be the primary evaluation strategy for new programs or those with limited resources. The drawback of this approach, however, is that it may be less accurate.

Conducting a cervical cancer control program evaluation involves (1) identifying measurable evaluation indicators (both process and impact), (2) deciding upon an appropriate evaluation strategy (for instance, comparing pre- and post-program levels of knowledge or activity), (3) gathering information about selected indicators, and (4) analyzing the information and reporting findings. Both quantitative and qualitative methods of data collection can be used.

A number of indicators can be used to measure a cervical cancer control program's activities and impact (see list of indicators, next page). For each indicator, evaluators must decide what constitutes success. Often this will depend upon the maturity and scope of the program as well as on the program's resources for implementing activities. For example, a newly formed program may consider itself successful if it can screen 30 percent of women

aged 35 to 50 in its first year of operation, while a more established program may define success as reaching at least 90 percent of these women.

To ensure maximum impact, evaluation results should be reported to appropriate program personnel along with recommendations for corrective action, if needed. For example, if an evaluation finds that few women referred for diagnosis are actually receiving diagnostic services, action should be taken to determine why women are not receiving diagnosis and to develop mechanisms to address the problem (for example, providing transportation to a clinic where diagnosis is provided, developing linkages with diagnostic providers, etc.). When discussing possible solutions to problems identified during an evaluation, involving individuals who provide or receive services and/or gathering more in-depth information about the problem can be helpful.

Efficient Information Systems Are a Must

Establishing well-functioning information systems is essential to successful program monitoring and evaluation. Client records should allow programs to follow individual women over time, including a client's screening results, diagnostic referrals, and treatment outcomes. Ideally, information from client records should be linked into regional or national databases to allow easy aggregation of data on key evaluation indicators. Where available, a national cancer registry can be used to monitor changes in cervical cancer incidence rates. Where no such registry is available, one can be initiated by first collecting data from a limited area and then gradually expanding the reporting area. It is not necessary for the registry to cover the entire population to generate adequate data for monitoring disease patterns, however.

Policy Implications

Evaluation is a necessary component of cervical cancer control programs. When establishing a program it is important to:

- ❖ Have a monitoring and evaluation plan in place from the start.
- ❖ Choose realistic and measurable indicators.
- ❖ Establish appropriate information systems to support monitoring and evaluation activities.
- ❖ Act quickly on evaluation findings.

In many cases it may be advisable to start slowly, gradually expanding the scope of monitoring and evaluation activities as the program becomes established.

Selected Evaluation Indicators

Process Indicators

Screening

- % of women aged 35-50[†] screened in past 5 years
- % of women aged 35-50[†] screened for the first time in past 5 years*
- % of designated health workers who perform or refer women for screening
- % of health facilities offering cervical cancer screening services*
- % of all screening tests positive for high-grade lesions of cancer*
- % of inadequate/inconclusive screening tests
- % of false-positive screening tests
- % of women aged 35-50[†] who recognize basic screening messages
- % of women aged 35-50[†] with positive attitude toward screening services*

Diagnosis and Treatment

- % of women with positive screening results diagnosed within 3 months
- % of women diagnosed with moderate/severe dysplasia treated within 3 months*
- % follow-up of treated women within 1 year
- % of preinvasive lesions treated with outpatient methods

Impact Indicators

- incidence of invasive cervical cancer
- mortality rate from cervical cancer

[†]A reasonable age group for new program with limited resources.

*Suggested minimum indicators for new programs.

Cervical Cancer Information Needs

A key challenge for programs is reaching women at highest risk for treatable, pre-cancerous lesions—typically women aged 35 to 50—with messages that encourage them to seek cervical cancer prevention services.

The messages should convey the following basic concepts:

- *cervical cancer is a serious but preventable disease*
- *as women grow older, their chance of developing cervical cancer increases*
- *screening tests can detect conditions that precede cervical cancer; these conditions can be treated easily*
- *women between the ages of 35 and 50 should be screened at least once*
- *being screened may help avoid serious disease requiring treatment such as hysterectomy*

Messages also should inform women about where screening can be obtained and what to expect if a treatable condition is detected.

Women who request screening services should receive additional information at the time of service about screening tests, the need for follow-up if a positive result is received, and the importance of repeat screening, if recommended.

In many countries, both women and providers lack information about cervical cancer prevention options. As a result, women may fear the disease but are not motivated to seek preventive services, or they do not know where they are available. Providers may adopt inappropriate medical protocols and use limited program resources inefficiently. Efforts to improve women's awareness and provider knowledge of prevention options are key to a successful cervical cancer prevention program.

Feasible Approaches in Low-Resource Settings

Increasing women's awareness. A key challenge for programs is reaching women at highest risk for treatable, precancerous lesions—typically women aged 35 to 50—with messages that encourage them to seek services. Because many women in this age group have completed childbearing and therefore are not likely to seek family planning or maternal and child health services regularly, special approaches often are needed to inform them of the need for and availability of screening. The best approaches for increasing awareness of cervical cancer prevention options among women in their postreproductive years will vary from place to place. Possible approaches include:

- ❖ Using established communication structures, such as the mass media.
- ❖ Reaching women through local women's or community groups.
- ❖ Linking screening to an important event in an older woman's life, such as becoming a grandmother.
- ❖ Linking screening to other mid-life health needs, such as contraceptive sterilization.
- ❖ Reaching women through their school-age children.
- ❖ Reaching women through their husbands, who may participate in community or employment-related activities.

The specific wording and presentation of motivational messages should be adapted locally and pretested with members of the intended audience to ensure that they are appropriate and easily understood.

Increasing provider knowledge and skills. Program success depends upon (1) assisting providers in adopting a public health-oriented approach to screening and treatment and (2) ensuring that they have the skills necessary to counsel clients and provide high-quality services that respect women's concerns and needs.

Experience from cervical cancer control efforts worldwide suggests that many providers follow service delivery protocols that are not appropriate for low-resource settings—for instance, screening women as frequently as every six months, focusing screening on younger women, and attempting to treat advanced cancers. Widespread use of such practices can prevent programs from making a significant health impact by draining program resources. Both pre-service and in-service provider training can address this issue by providing clear information about the public health rationale for limiting the frequency of screening, focusing on older women, and emphasizing treatment of precancerous conditions. Enlisting the support of respected physicians or medical associations in this effort is important.

Appropriate counseling is a critical component of cervical cancer control services. Essential to effective counseling is establishing a respectful rapport with women so that they can get the information they need and feel comfortable returning for required follow-up visits.

Policy Implications

In developing effective mechanisms to increase women's awareness of and providers' knowledge about cervical cancer prevention services, programs should consider the following issues:

- ❖ Ensure that outreach efforts reach the majority of women aged 35 to 50 (including difficult-to-reach populations such as poor, urban women; women in remote areas; and low-literate women).
- ❖ Develop key messages and communicate them in a culturally acceptable way.
- ❖ Ensure that providers and health decision makers receive information about and support a public health-oriented strategy of limited, targeted screening and appropriate treatment strategies.
- ❖ Train providers (including non-physicians) in counseling and interpersonal communication skills so that they may inform women sensitively and respectfully about the screening process; the meaning of the result; and appropriate follow-up steps, when necessary.

Effective Counseling and Interpersonal Communication Skills

- listening to and responding to client concerns
- maintaining a non-judgmental and respectful attitude
- encouraging questions and discussion

Introduction: Considerations for Program Design

The following section is designed to provide guidance to programs considering launching a cervical cancer control program. Key areas are:

- ❖ Assessing existing program environment and capabilities important to cervical cancer control.
- ❖ Ensuring that a new program includes a minimum package of services essential to ultimate program impact.
- ❖ Following key steps in program planning.
- ❖ Identifying and evaluating the cost implications of cervical cancer control.

Considerations for Launching an Effective Cervical Cancer Control Program

Program planners need to consider the minimum level of services required to reduce cervical cancer morbidity and mortality when deciding whether and how to launch a cervical cancer control program. The technical and financial resources available to a program, as well as the health care infrastructure already in place, are key determinants of whether a minimum set of cervical cancer control services can be established. Systematic consideration of these factors will help decision makers assess the feasibility and appropriateness of initiating new services or expanding existing services.

Existing Program Environment and Capabilities

Before embarking on any new health program, it is important to verify the need for services and assess the program environment and existing capabilities.

Where available, cervical cancer incidence data (from national or local records) can help decision makers **verify the need** for cervical cancer screening and treatment services, particularly in comparison to other health priorities. In general, an age-standardized incidence level greater than 30-40/100,000 women indicates a strong need for these services. A high prevalence of sexually transmitted disease (STD) (for instance, a syphilis, gonorrhea, human papilloma virus, or chlamydia incidence greater than 8 percent) also indicates need. Where national or local cancer or STD incidence data are not available, discussions with health care providers can help decision makers get a sense of the magnitude of the problem.

Decision makers also should **assess the local environment and service delivery capabilities** that might affect initiation of cervical cancer services. In some cases, strong community support and complementary existing services will provide a solid foundation for initiating services. In others, provider biases and a weak infrastructure may make even basic cervical cancer services infeasible. The assessment can be done using a combination of existing data on clinic services and facilities, small-scale provider surveys, and a limited number of focus group discussions or in-depth interviews with women, providers, and key community members. It should include the following elements:

- ❖ *Assess the level of political, provider, and community support for initiating services.* Important points to assess include whether policy makers, service providers, and community leaders understand and agree with a public health approach to cervical cancer control (i.e., where resources are scarce, using targeted and infrequent screening combined with outpatient treatment of precancerous lesions); support preventive care, particularly for older women; see cervical cancer as a priority compared to other health needs; and are willing to allocate financial resources to cervical cancer control efforts.
- ❖ *Assess existing service delivery capabilities and system infrastructure.* This includes the number and location of clinic and hospital facilities and their ability to take on new responsibilities for screening and treatment; level of staff expertise and training; availability of necessary equipment and supplies; availability, capacity, and reliability of cytology laboratory services; and availability and functioning of referral networks.

- ❖ *Assess the level of awareness of cervical cancer among women aged 35 to 50. Key points to assess include women's perceptions and misperceptions of cervical cancer as a health problem, awareness and acceptability of prevention options, preferred information sources, preferred service delivery sites, and linkages to community groups and services.*

The information gained during such an assessment will be helpful not only in deciding whether to proceed with initiating services, but also in designing services (see box below).

Using Assessment Results to Guide Program Development

Information from an assessment of local environment and capability can provide useful guidance to program managers in formulating strategies for providing cervical cancer information, screening, and treatment services. In many cases the assessment will uncover challenges to offering services that can be addressed through program activities. Some examples of common assessment findings and the types of actions that can be taken to address those findings are listed below.

Findings

Possible Action

Providers favor frequent screening of women starting at age 18.

Provide information about the health and cost rationale for focusing screening on women in their middle years.

Women fear that they will receive "bad news" from screening.

Design reassuring messages that emphasize that screening helps women avoid serious disease.

Facilities with treatment equipment are available only in major urban areas.

Make outpatient treatment equipment available to smaller provincial or district centers for special outreach treatment sessions.

Minimum Level of Services Required

To be effective, a cervical cancer control program must consist of a package of education, screening, and treatment services that reach the majority of targeted women. Implementing any one of these elements without the others does not make sense and would not have substantial positive impact. For example, screening services must be supported both by educational efforts (to motivate women to seek screening services) and by treatment services (to ensure that disease identified through screening is appropriately managed).

At a minimum, programs must be able to reach women at highest risk of cervical dysplasia (those aged 35 to 50 are a reasonable starting point) with effective educational messages, screen those women at least once, and provide appropriate treatment or palliative care to those who need it (see Figure 1). Experience suggests that a management information system also must be in place at the onset of program activities for maximum program efficiency and impact. The specific financial and technical inputs needed to achieve this program initiation threshold (number of providers, cytologists, etc.) will depend on the size of the population to be served and the existing health infrastructure.

Figure 1. Program Initiation Threshold: Minimum Program Goals and Necessary Inputs to Achieve Them*

Information, Education, and Communication

Basic goal: Increase awareness of cervical cancer and preventive health seeking behavior among women aged 35 to 50.[†]

Necessary inputs:

- Proven mechanisms for (1) increasing awareness of cervical cancer and available prevention services among women aged 35 to 50 and (2) motivating women to seek out screening services and treatment, when needed.
- Providers trained to counsel women about the Pap smear process and provide respectful, confidential services.

Screening

Goal: Screen all women aged 35 to 50 at least once. (Inputs are based on a cytology-based program and may change if alternative screening approaches are proven effective.)

Necessary inputs:

- Trained Pap smear providers (including non-physicians).
- Pap smear supplies (swabs, slides, fixative, etc.).
- Pelvic exam equipment (tables, specula, light source, etc.).
- Reliable cytology laboratory, including trained cytologists.
- Proven mechanism for timely communication of Pap smear result to provider/client.
- Effective referral system for diagnosis and treatment.

Diagnosis and Treatment

Goal: Treat women with high-grade dysplasia, refer those with invasive disease where possible, and provide palliative care for women with advanced cancer.

Necessary inputs:

- Providers (including non-physicians where appropriate) trained in cervical visualization and treatment of high-grade dysplasia/carcinoma *in situ*.
- Colposcopes or other appropriate means of visualizing the cervix.
- Treatment equipment (cryotherapy or loop excision) for high-grade dysplasia.
- Centrally available surgical treatment for early invasive cancer.
- Palliative care for advanced cancer (pain control and counseling).

Monitoring and Evaluation

Goal: Collect service delivery statistics that will facilitate ongoing monitoring and evaluation of program activities and outputs.

Necessary inputs:

- Local information system for tracking number and identities of women screened, cytology results, and follow-up actions and results
- Clinical registry of Pap smear results.

* The level of input needed (for instance, the number of trained Pap smear providers) will depend on the size of the population being served and on available resources and health care infrastructure.

[†]35 to 50 is a reasonable target age group for a new program with limited resources. As the program matures, the age group can be expanded first to older women (up to age 60) then to younger women (from age 30).

Key Steps in Program Planning

When deciding whether to initiate cervical cancer prevention services, decision makers must compare information on existing capabilities/infrastructure with the estimated inputs needed to achieve the minimum service delivery goals for a given population (see Figure 1). Programs can then define the additional technical and financial resources needed to initiate program activities and determine whether these resources are available. Programs that are unable to meet a minimum service level should delay initiation of services until the level can be achieved.

- ❖ The first step in making this comparison is to define the target audience for program activities. As mentioned, a reasonable target group for a new program is women aged 35 to 50. Furthermore, most new programs will want to limit the geographic scope of their activities initially, starting in a well-defined area and then gradually expanding to other regions as technical capabilities and financial resources allow. Information from the assessment can help program planners decide where to target services by identifying areas with the greatest need and readiness.
- ❖ Once the size and composition of the target population has been established, programs can quantify the inputs (number and type of personnel, equipment, and facilities) that will be needed to meet information, screening, and treatment needs. To accomplish this, program planners should consult with service providers (reproductive health care providers, cytology laboratory personnel, etc.) to determine what would be required to meet the program's service delivery goals. For instance, cytology laboratory staff will be able to estimate the resources (staff, equipment, and supplies) required to process a given number of Pap smears and compare these estimates to existing service capacity.
- ❖ After quantifying the inputs needed to achieve a basic level of services, program planners need to estimate the costs of providing these services (see next section). Costs will vary by location according to the local costs of supplies, availability of equipment and facilities, and current skills and efficiency of program personnel. If many of the inputs needed to achieve the basic level of services already exist in the service area, the costs of adding cervical cancer control services may be minimal. On the other hand, if considerable equipment, facilities, and training programs are needed, start-up costs could be quite high. If costs appear to be a major barrier, it is important to estimate how much a health care system currently may be spending on treating cervical cancer cases (surgical, hospitalization, radiotherapy costs, etc.) before deciding against a program. Limited health resources are better spent on efforts to prevent cancer from occurring than on treatment of advanced cases, which is costly and rarely successful.

Programs that have additional financial resources or are operating in the context of a relatively well-developed health infrastructure can consider expanding beyond the basic goals listed in Figure 1. If this is the case, program managers should determine feasible approaches to expanding the program's scope given available resources, including:

- Increasing the percentage of women in the high-risk age group that attend screening services.
- Expanding the targeted age group first to older women (up to age 60) and then to younger women (from age 30).
- Decreasing the interval between screenings of high-risk women.
- Improving the availability of treatment services to reduce the distance that referred women must travel for care.

Cervical Cancer Control: Cost Considerations

The cost implications of cervical cancer control must be taken into account when planning for a new or expanded cancer screening program. Programs generally are interested in a range of cost information, including:

- ❖ The yearly incremental costs of providing cervical cancer services as part of integrated women's health services.
- ❖ The cost-effectiveness of offering effective cervical cancer interventions (for example, the cost per life saved, cost per case detected).
- ❖ The relative cost-effectiveness of cervical cancer interventions compared with other important health interventions.

Addressing the first issue requires calculating the expected expenditures of a given cancer control strategy, including necessary capital expenditures (annualized or depreciated) and regular incremental expenditures (staff, supplies, and other ongoing needs beyond what already is available) for both screening and treatment interventions. An accurate cost analysis also requires an understanding of dysplasia prevalence, the average dysplasia-cancer progression rate, and the effectiveness of proposed screening and treatment interventions. Some expected expenditures may decrease over time with economies of scale, others may increase; these types of changes need to be considered. The example from South Africa on page 3-6 illustrates the considerations and results of this type of analysis.

To address the second issue, a cost-effectiveness analysis can be carried out in which the expected expenditures described above are compared with the potential benefits of a new intervention. This analysis produces a cost-effectiveness ratio of costs to health benefits (i.e., cost per cases detected, lives saved, or other benefit). The example from Chile on page 3-7 demonstrates how cost-effectiveness ratios can be useful in highlighting differences between two proposed program approaches. Where cost-effectiveness analyses have been carried out for interventions for other health problems, cost-effectiveness ratios can be compared to help assess the costs of cervical cancer control strategies relative to other health interventions (see page 3-7).

Completing cost-effectiveness analyses for cervical cancer control requires accurate data on the expected capital and incremental expenditures for a new intervention and agreement on a range of assumptions related to the proposed control strategy. The assumptions include prevalence of cervical dysplasia and invasive cancer, the dysplasia-cancer progression rate, sensitivity of the screening approach, effectiveness of the dysplasia treatment approach, and the time frame of the analysis. Furthermore, programs must have (or acquire) the technical capability to gather necessary data and carry out the calculations involved in cost analyses.

Once a cost analysis is completed, the next challenge is to interpret the results. It is key to understand that parameter selection can have a significant effect on the results of an analysis. For example, in general:

- Assuming a higher baseline incidence of cervical cancer will increase cost-effectiveness.
- Assuming a lower screening sensitivity will lower cost-effectiveness.
- Assuming a higher program coverage will increase cost-effectiveness.
- Assuming an adequate existing health infrastructure will increase cost-effectiveness.

Most importantly, program managers must recognize that cost-effectiveness results are an aid to decision making, not the key component. A variety of medical, ethical, cultural, and practical considerations also are important to making an appropriate decision regarding allocation of health resources.

While a thorough explanation of cost analyses is beyond the scope of this document, this section provides examples of how various cost analyses have helped programs to make decisions about different strategies, and outlines how a computer program can aid in understanding the cost implications of various program approaches. The section also provides guidance on the cost implications of specific screening and treatment strategies. For detailed information on general cost analysis strategies, the following references will be useful:

Gold, M.R., et al. (eds.) *Cost-Effectiveness in Health and Medicine*. New York and Oxford: Oxford University Press, 1996.

Brenzel, L. *Selecting an Essential Package of Health Services Using Cost-Effectiveness Analysis: A Manual for Professionals in Developing Countries*. Data for Decision Making Project: Harvard University, 1993.

Examples of Cost Analyses of Cervical Cancer Programs

South Africa: Cost Analysis Highlights Value of Screening

As part of a comprehensive evaluation of factors affecting cervical cancer screening in South Africa, an analysis of total costs of program implementation was completed. While the estimated program costs are higher than in many other African countries (for example the estimated total cost of a single screening in Zimbabwe is \$3.50, in Kenya \$3.00), this cost analysis is a useful example of how total costs information can be used. The analysis quantified the costs of:

- Screening (obtaining/reading Pap smears) - US\$22 per screening by a specialist, \$11 per screening by public sector.
- Dysplasia treatment (colposcopy and laser or cryotherapy) - \$89 per treatment.
- Treatment for invasive cancer (biopsy, hysterectomy, radiotherapy) - \$3,573 per case.

The analysis then compared the total costs of two program approaches: (1) one that did not attempt to screen women, but instead focused on treating women with symptomatic, invasive cancer and (2) a second that screened women and then treated both precancer and cancer. According to the analysis, the first approach of treating only invasive cancer would cost over 80 percent more than a screening program using public-sector providers. When specialists were used to perform screening, the cost saving was only 12 percent. (The analysis assumed a 2 percent CIN prevalence and a 50 percent CIN progression rate, which are reasonable assumptions given the limited data available on cervical dysplasia in South

Africa.) Even when the prevalence was assumed to be 1.5 percent or the progression rate was assumed to be 25 percent, a screening program using public-sector facilities still was less expensive than a program based on treatment only. Lowering both assumptions made a public-sector screening program the more expensive option.

(Source: Fonn et al. *Towards a National Screening Policy for Cancer of the Cervix in South Africa*. Paper N-31, February 1993.)

Cost-Effectiveness of Two Screening Strategies in Chile

The cost-effectiveness analysis illustrated below compares two different strategies for cervical cancer screening in Chile. The comparison illustrates the relative effectiveness of less frequent screening of most at-risk women compared with more frequent screening of fewer than half of at-risk women. This type of analysis can be useful to program managers in deciding what program strategies to implement.

	Program 1	Program 2
Age	30-55 years	30-50 years
Frequency of screening	3-yearly	10-yearly
Coverage	30%	90%
Reduction in mortality	15%	44%
Cost per case detected	US\$2,522	US\$556

(Source: Eddy, 1986, as described in Miller, *Cervical Cancer Screening Programmes: Managerial Guidelines*. Geneva: WHO, 1992.)

Comparing the Cost-Effectiveness of Cervical Cancer Screening to Other Health Interventions

To be useful, any health cost analysis must consider other health needs. In most developing countries, there are many serious health needs that “compete” for available resources. Where cervical cancer is a serious problem, other women’s health problems probably exist, for example maternal morbidity and mortality; reproductive tract infections, including human immunodeficiency virus (HIV); and tuberculosis. Serious children’s health problems may include neonatal morbidity and mortality, diarrheal disease, various other infectious diseases, and nutritional deficiencies.

The most recent data suggest that cervical cancer is among the top five causes of death among developing world women aged 45-59 (along with tuberculosis and cardiovascular diseases). Even for women aged 30-44, it is among the top ten causes of death (with tuberculosis, obstetric, cardiovascular, cirrhosis, and HIV deaths rated higher). The World Bank has identified cervical cancer as a moderately cost-effective intervention compared with other health interventions, and a very cost-effective intervention compared with other cancer control efforts. The Bank estimated that screening women at five-year intervals would cost about \$100 per disability-adjusted life year (DALY[†]) gained (assuming that an appropriate referral system for necessary treatment exists). This amount is a fraction of the

[†] DALYs are a measure of life years gained that combine the number of years of healthy life lost due to both premature morbidity and mortality, using a set of age and disability estimated weights.

estimated costs of cervical and breast cancer treatment. Compared with some other interventions, however, cervical cancer screening is relatively expensive.

The brief list below illustrates how the costs of cervical cancer screening compare with costs of other health interventions.

Intervention	Cost per DALY (US\$)
Lung cancer prevention (smoking cessation programs)	20
Polio vaccination	20 in a high-mortality environment 40 in a low-mortality environment
Sexually transmitted disease management	1-55
Cervical cancer screening	100
Integrated antenatal/delivery care for maternal mortality	30-250
Malaria treatment	200-500
Malaria control (through mosquito control)	5-250 depending on mosquito type
Cervical cancer treatment/palliative care	2,600

(Sources: Jamison et al., eds. *Disease Control Priorities in Developing Countries*. Oxford University Press, World Bank, 1993; Murray and Lopez, Global and regional cause-of-death patterns in 1990. *Bulletin of the World Health Organization*. 72(3):447-480 (1994).)

*Cost Implications of Various Cervical Cancer Control Strategies: An Example Using the CAN*TROL Program*

Predicting the most cost-effective approach to controlling cervical cancer in a given setting can be a difficult, time-consuming endeavor. Computer software can make modeling various approaches much quicker and easier. One tool, the CAN*TROL software program, may be quite useful in some settings (see Potosky et al., 1995, in the bibliography for contact information). Developed initially by Dr. David Eddy and the World Health Organization, and further refined by the U.S. National Cancer Institute, it is designed to calculate the effects of implementing various prevention, screening, and treatment interventions on cancer incidence, prevalence, and mortality as well as on expected costs and cost-effectiveness outcomes.

Using the CAN*TROL program to simulate the impact of various cancer interventions, it is possible for program managers to estimate the health and financial consequences of different strategies. To use the program one must be able to provide (or estimate) the age structure of the local population, age-specific cancer incidence rates, age-specific general mortality rates, the likely survival rates for different stages of the cancer, and typical costs for specific screening and treatment interventions. When such information is entered into the program along with estimates of the expected coverage and effect of the intervention, a summary table is produced showing how many lives would be saved over a given time period, the discounted net costs (costs minus savings) associated with the intervention, and cost per life year saved. By adjusting values of specific variables (e.g., the cost of screening or treatment, or the effectiveness of the proposed intervention), the manager can then use the program to predict the effect of changing specific variables within a given model.

For example, using population, cancer, and cost data estimated from various Southern Africa sources around 1990 (approximate population of 43 million), the effect of varying approaches to dysplasia screening by Pap smear for women aged 35-55 was evaluated, assuming a baseline screening coverage of 5 percent. Three models were run for a 20-year period changing only the coverage or timing of the intervention:

- Forty percent coverage from the start.
- A phased-in coverage over three years with levels of 50, 65, and 80 percent, respectively.
- Eighty percent coverage from the start.

The models included several assumptions that may not be realistic (for example that all women with cancer will receive at least surgical treatment); nevertheless the results outlined below are helpful in clarifying the health and cost implications of different strategies.

Percent Change over 20 Years from a Baseline Screening Coverage of 5%

Screening Coverage*	Lives Saved (discounted)[†]	Life-years Saved	Cumulative Net Savings^{††}
40%	+574%	+569%	+514%
3-year phased (50/65/80%)	+843%	+811%	+629%
80%	+939%	+938%	+700%

* among women aged 35-55

[†] cumulative deaths averted over 20-year period, discounted 5% each year

^{††} compared with the cost of treating invasive cancer

In general, the program demonstrated that, compared with the costs of treating invasive cancer, a simple screening strategy using established screening methodology would result in significant savings. Doubling screening coverage significantly influences the health and cost impact of the program; phasing in screening over several years has a smaller impact.

Cost Implications of Selected Screening and Treatment Strategies

Screening

Screening costs vary according to the cost and accuracy of the method selected, the populations screened, screening frequency, and recruitment strategies adopted.

- ❖ **Method:** The cost-effectiveness of screening approaches is affected by (1) clinical procedures with patients, (2) screening and laboratory analysis costs, and (3) accuracy of the screening technology.
 - **Pap smears:** Cytologic screening based on Pap smears is the most widely used screening method. Estimates of Pap smear costs in developing countries range from US\$3-US\$10 (cost includes Pap smear sampling and analysis). Smear analysis conducted by cytopathologists in addition to or instead of cytologists is much more expensive than relying on trained cytologists with cytopathologist back-up. Pap smear accuracy varies widely as it is influenced by sample quality and by laboratory capability. Cost-effectiveness can be significantly compromised if Pap smear quality is poor.

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- Cervicography: Currently, the high cost of this system (in which photographs of the cervix are taken and then evaluated by trained technicians) is driven by high capital costs (colposcope, special camera) and interpretation costs (the film must be sent to a central facility to be developed and read). If ongoing research shows cervicography to be highly accurate, however, its cost-effectiveness could compare favorably to other methods.
 - Visual inspection: If validated, this approach, with or without magnification, likely would be an inexpensive screening option since only acetic acid (for swabbing the cervix) and, if used, a small, reusable, magnifying device (<US\$50), are needed. Further research is required, however, to evaluate the effectiveness of this approach.
 - HPV testing: Currently, DNA testing for human papilloma virus as a marker for cervical cancer risk is conducted primarily in research settings. Available tests cost between US\$3 and US\$5 per test and require sophisticated equipment. New test generations likely will be easier and cheaper to use, and results of ongoing research should clarify how HPV testing could be used most effectively in screening programs. Low- and middle-income countries, however, should continue to focus on achieving screening coverage through less expensive means.
- ❖ Target population: Cost-effectiveness is increased where target populations have higher dysplasia rates. In general, women aged 35 to 50 are at highest risk and provide the highest yield of abnormal results, which increases screening efficiency.
 - ❖ Frequency of screening: Screening women relatively infrequently is cost-effective. Screening women every 10 or every 5 years reduces the cumulative cervical cancer rate by 64 percent and 84 percent of cancer cases, respectively, according to the World Health Organization. Screening every year results in a relatively small incremental decrease in cancer and is much less cost-effective.
 - ❖ Recruitment approach: To reach women for screening, programs must determine whether to rely on active or passive recruitment methods. Active outreach is more expensive but may increase coverage among high-risk groups and therefore increase screening efficiency. Passive or opportunistic recruitment does not require any additional expense and may be appropriate in settings where high-risk women already are being seen for other services.

Dysplasia Treatment

Dysplasia treatment costs vary according to the cost and accuracy of the method selected, the service delivery strategy, type of provider, the grade of dysplasia treated, and the rate of side effects and complications.

- ❖ Treatment methods: Outpatient methods like loop excision (LEEP) and cryotherapy are less expensive, similarly effective, and have fewer complications than methods such as cone biopsy and hysterectomy. All, however, require colposcopy or an alternative method to visualize the cervix. Colposcopes can cost up to US\$20,000 per unit.
- Cryotherapy: Initial costs for cryotherapy range from US\$1,000 to \$3,000, while recurrent costs (for refrigerant and other consumable supplies) are generally low. Non-physician providers could be trained in the method, which reduces salary costs, and electricity is not required, which reduces overhead. This approach, however, is

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- sometimes less effective (80-90 percent) in treating CIN III compared to other methods.
- LEEP: Initial costs for LEEP range from US\$4,000 to US\$6,000. Recurrent costs are moderately high and include loops (US\$15-US\$60 per loop), local anesthesia, electrodes, and smoke evacuator. The method is highly effective (90 to 95 percent) in treating all CIN grades, which may offset its relatively higher initial costs compared to cryotherapy.
 - Cone biopsy and hysterectomy: Both of these methods are inpatient procedures and require sophisticated training and equipment. General anesthesia also is required, which can be very costly. Further, serious side effects and complications such as bleeding, cervical stenosis, spontaneous miscarriage, and infection are associated with these approaches. In developing countries, clients may be charged \$75 or more for cone biopsies and \$1,500 for hysterectomies.
- ❖ Service delivery strategies: Options include central, district, or mobile delivery of treatment services. The most cost-effective approach will depend on staff availability, distance and ease of travel, and availability of equipment and supplies. Centrally based services shift the cost of travel to the client, but follow-up rates may be lower, which could undercut the value of screening.
 - ❖ Provider: Currently, physicians generally provide CIN treatment. Use of non-physicians such as nurses, however, could reduce costs and increase the availability of services.
 - ❖ Grade of dysplasia treated: Because more than half of low-grade dysplasias regress without treatment, maximum cost-effectiveness may be achieved by treating only moderate and severe (or only severe) dysplasias.

Cancer Treatment

Treating cancer is generally very expensive and often not successful. Hysterectomy and radiotherapy, if available, are recommended for early-stage cancer. Depending on availability, these services can cost hundreds or thousands of dollars to the patient. For late-stage cancer cases, palliative care (including counseling and pain control) is recommended, which includes the cost of medication, counselors, and, in some cases, hospitalization. Aggressive care for all cancer stages would be the other, considerably more expensive option. In many countries, the limited cancer funds in many countries are used to buy chemotherapeutic drugs and radiotherapy equipment, rather than to support improved detection and treatment of preinvasive conditions.

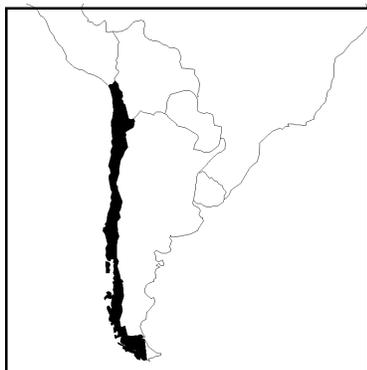
Introduction: Project Summaries

In the following section, seven summaries of cervical cancer programs, interventions, and studies undertaken in a variety of countries are presented. These summaries represent a wide range of approaches; some are relatively well-funded and are national or regional in scope, while others are local, clinic-based efforts. Several summaries also illustrate the role of research in developing effective programs.

In addition to project descriptions, all summaries provide information on the challenges faced by providers and program managers in implementation, as well as the implications of these efforts for other programs. Some of the common themes that emerge from these summaries include the importance of:

- ❖ strong management and long-term commitment at all levels of the health care system, as well as supportive health policies;
- ❖ educating at-risk women about cervical cancer and involving potential clients and the community in program planning to ensure client concerns and cultural constraints are addressed;
- ❖ coordinating/integrating cervical cancer prevention efforts with other services and/or programs;
- ❖ providing initial and refresher training for key personnel, including non-physicians, cytologists, and others; and
- ❖ adequate information systems and quality control protocols to facilitate program monitoring and evaluation.

Contact information for the managers of each program or project is provided at the end of each summary so that readers may directly request additional information about these various efforts.



Chile: two decades experience in cervical cancer screening

Chile began working toward a cervical cancer screening, diagnosis, and treatment program in the 1960s; only in the past decade, however, has a coordinated program with monitoring and evaluation been implemented. Having data to show the impact of services has helped the cervical cancer prevention program win official recognition and greater government support.

Cervical cancer is one of the leading causes of mortality in women over 35. Data from the early 1980s suggest Chile's cervical cancer death rate (about 14 per 100,000 women) ranked among the highest in the Americas. The incidence of invasive cervical cancer in Chile for women over 25 years of age from 1988-1994 was around 33 cases per 100,000 women. From 1970 to 1994, program evaluation data revealed that the age-adjusted mortality rate had decreased from 13.3 to 9.2 per 100,000 women. Since 1993, cases of carcinoma *in situ* have been found at a higher frequency than cases of invasive cancer, suggesting that early detection efforts are working.

Program Description

The National Public Health System (NPHS) is comprised of 26 Health Services, each with its own geographic area. The NPHS first began offering Pap smear services in 1964 but received little coordination or program guidance from the Ministry of Health (MOH). Women attending maternal and child health care clinics were offered annual Pap smears, even though those clinic populations were primarily young women and, therefore, at relatively low risk for cervical cancer. The screening services languished from lack of coordination, monitoring, and evaluation. Since the programs were not evaluated, impact of the screening and treatment services was not known, and resources could not be efficiently targeted.

In 1985, the program received a boost when the MOH initiated a National Cancer Control Program, targeting cervical cancer as a priority. A year later, it implemented the World Health Organization guidelines for cervical cancer screening and control. The main program objectives were:

- ❖ Eighty percent coverage of women aged 25 to 64 years with a Pap smear every 3 years.
- ❖ Fifty percent of women identified as high-risk requesting Pap smears every 3 years.

This program has gained strength by working through the NPHS health system on a clinic-by-clinic basis to promote Pap smear screening in three ways:

- ❖ promoting screening among female health care providers themselves (coverage increased from 43 to 80 percent in 10 years);
- ❖ promoting screening among "high-risk" women attending clinics other than the maternal and child health clinics (coverage increased from 43 to 72 percent); and
- ❖ promoting screening through community-based outreach and education among high-risk women not attending primary health care centers (coverage increased from about 30 percent in 1992 to nearly 50 percent in 1995).

Additionally, beginning in 1996, most of the Health Services have computer software that allow them to monitor and evaluate program activities.

By the year 2000, the program hopes to have reduced cervical cancer morbidity and mortality by 50 percent through improved program coordination, early diagnosis and treatment of abnormal Pap smears, education and training, and improved quality control and monitoring of cytology procedures. In 1995, a National Reference Cytology Laboratory was established and 22 public laboratories participate in the quality control system. Private laboratories will be incorporated as resources allow.

Program Challenges

The major challenges identified by the Chilean program are listed below:

- ❖ retaining highly motivated and trained professionals in the program;
- ❖ keeping resources focused on high-risk groups;
- ❖ improving registration of pre-invasive and invasive cancer;
- ❖ allocating adequate resources for community work, mass media, and cytology labs to continue increasing coverage;
- ❖ overcoming cultural barriers to having Pap smears;
- ❖ including private labs in the cytology quality control program; and
- ❖ integrating services with other women's health promotion programs.

Implications for Other Programs

Some of the key lessons learned from efforts to strengthen cervical screening and treatment services throughout Chile are described below.

- ❖ Any screening program should follow the principles of public health interventions from the beginning. It took 20 years to realize that screening of cervical cancer in Chile was having little impact, and another 8 years to convince the majority of health care professionals that new strategies were research-based and cost-effective.
- ❖ Success breeds success. Better coordination and guidelines, improved quality control, and more focused screening have helped the program optimize resources and become successful. As the program has shown improved results, the government has been more willing to provide administrative and financial support.

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Colombia: a recent nationwide effort to reduce cervical cancer incidence

Colombia is in the midst of an epidemiological transition, and many aspects of women's health are improving markedly. Yet cervical cancer remains a serious health problem throughout the country, despite efforts to make screening more widely accessible.

During the period 1989-1991, cervical cancer was the leading cause of cancer deaths in urban women, and second only to stomach cancer in rural women. Overall, cervical cancer was the eighth most common cause of death among urban women and tenth among rural women. Furthermore, available data suggest that the mortality rate from cervical cancer has not decreased since the early 1960s, and may even have increased somewhat. In 1985, cervical cancer incidence rates in Cali (where the only population-based cancer registry in the country is maintained) were among the highest of all population-based registries worldwide.

Program Description

The Colombian public health system, private organizations such as PROFAMILIA (a family planning nongovernmental organization), and the Colombian National League Against Cancer have been offering Pap smears since the mid 1970s. Yet, as described above, these efforts did not seem to have an impact on cervical cancer morbidity and mortality. In 1990 a five-year, nationwide cervical cancer control program was initiated with the goal of reducing the incidence of invasive cervical cancer by 25 percent. The three main program objectives were to:

- ❖ Provide Pap smears to 60-90 percent of women aged 25 to 69 within a three-year period, with special emphasis on reaching women of low socioeconomic status.
- ❖ Provide follow-up to 90 percent of all women obtaining Pap smears through the program.
- ❖ Establish reference centers for diagnosis and treatment of women with precancerous lesions.

The program was integrated into existing health services. Over 4,000 nurses, 39 gynecologists, and 36 pathologists received clinical training; supplies and equipment were purchased; and information, education, and communication strategies were aimed at educating communities about cervical cancer. Efforts to educate communities included workshops involving local health services and influential women in the community. The program also worked to centralize cytology services and standardize cytology protocols and procedures.

It has been difficult to evaluate program objectives to date. Even with investment in computers and software, the flow of information from local to central levels has been slow. Results of national surveys, however, suggest that the program may be having an impact. Demographic and Health Survey and other data suggest that the proportion of women aged 20 to 49 who had ever had cytology increased from about 57 percent in 1990 to about 69 percent in 1993. Because the program is specifically trying to reach women over age 35, surveys focusing on this age group are being planned.

Program Challenges

The major challenges of Colombia's new cervical cancer control program are listed below:

- ❖ Expanding cervical cancer screening to women beyond their childbearing years. [The health system has traditionally offered cervical cancer screening primarily to women during their peak childbearing years, which, in Colombia, is before age 35.]
- ❖ Training enough cytologists to meet program demand. [There continues to be a shortage of trained cytotechnicians, particularly in certain parts of the country. Pressure from the medical pathologists association for a mandatory four-year training program in cytotechnology has complicated efforts to train more cytotechs quickly.]
- ❖ Improving quality of care, particularly in terms of treating women with respect and paying attention to their concerns. [Efforts are underway to integrate quality-of-care issues into all program components.]
- ❖ Developing an effective information system so that the impact of the program on Pap smear coverage and, ultimately, mortality and morbidity can be evaluated.

Implications for Other Programs

Some of the key lessons learned from efforts to expand cervical cytology services throughout Colombia are described below:

- ❖ Bottlenecks to program implementation should be identified at the start. In the Colombian program, the shortage of cytotechnicians was a key barrier to meeting program needs. In addition, the growing demand from women asking for Pap smears put pressure on the system to train more cytologists. In most countries, developing systems to ensure the growing availability of cytotechs is a key program need.
- ❖ It is crucial to develop an effective information system that allows for regular evaluation of program activities and achievements. This evaluation allows for identification of both program successes and program activities that need to be improved.
- ❖ Women living in poorer, less accessible areas are often at highest risk for cervical cancer. Special strategies to reach these women must be devised. In Colombia, strategies such as special "cytology days" in shanty towns have been initiated using radio, megaphones, and church calls to encourage women to attend.
- ❖ It is important to remember that the challenges of offering effective cervical cancer screening, diagnostic, and treatment services are not primarily technical challenges, but rather social and cultural ones. In short, cultural issues in local communities and in the medical/health communities can influence program success. Dr. Margarita Ronderos Torres concludes that "working together, respecting each other to deliver technology safely, efficiently, and effectively, is probably the key to success."

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Costa Rica: researching cervical neoplasia in a high-risk area

Guanacaste is a rural province in northwest Costa Rica. The estimated total population of Guanacaste in 1993 was 240,000 inhabitants (about 8 percent of the population of Costa Rica). General mortality in the region in 1990 was fairly low—about 3.7 per 1,000 inhabitants. Infant mortality was moderate at 14.6 per 1,000 live births, and life expectancy was good at 73.6 years.

Guanacaste has reported consistently high rates of invasive cervical cancer, despite the existence of a national cervical cancer screening and treatment program. During the five-year period from 1988 to 1992, incidence rates of invasive cervical cancer ranged from 23.5 to 45.1 per 100,000 women. This is higher than average in Costa Rica and at least four times higher than comparable rates in the United States. The main difference between high- and low-incidence areas in Costa Rica may be related more to varying prevalence of risk factors than to the intensity of screening.

Program Description

Costa Rica offers cervical cancer screening and treatment through the Bureau of Social Security of Costa Rica (CCSS), the main government health care provider in the country.

In an attempt to better understand why cervical cancer incidence in Guanacaste has remained high despite availability of screening and treatment, the Costa Rican Foundation for Education in Medical Sciences—a part of the CCSS—is implementing a six-year study in Guanacaste province to investigate the role of HPV infection and its co-factors in the etiology of high-grade cervical neoplasia, and also to evaluate new cervical cancer screening technologies. This study is being carried out in collaboration with (and with funding from) the U.S. National Cancer Institute.

Since the study began in 1992, more than 10,000 women have been enrolled. Each woman has had a pelvic exam, visual inspection of the cervix, and a conventional Pap smear. In addition, three new cervical cancer screening technologies have been used: (1) preparation of a liquid buffer-based ThinPrep® slide, which has been promoted as an improvement over standard Pap smear preparations; (2) collection of additional cells for human papilloma virus (HPV) DNA studies; and (3) cervicography (taking a special photograph of the cervix, which is then evaluated in a central lab).

Women with low-grade cervical lesions are scheduled to be rescreened every six months. Women with atypia and women who report five or more sexual partners, women with a positive HPV test, and a subset of normal women (without lesions or risk factors) are rescreened annually. Women with high-grade dysplasia in any of the screening tests were referred to the CCSS for proper treatment and not included in study follow-up.

The program has achieved high participation rates in all phases of the study, including follow-up. The available study resources, which have allowed personal visits to women

who need follow-up as well as an “open house” policy allowing participants to get convenient appointment dates (and travel expenses to the appointment, if necessary), have been key to this success. Also, study personnel have been specially trained to provide sensitive, high-quality care.

Program Challenges

The major challenges encountered during this research project are listed below:

- ❖ Limited experience of investigators and administrators with regard to contract negotiation and management.
- ❖ High cost of maintaining the number of full-time staff necessary to achieve high follow-up rates.
- ❖ Ensuring standard protocols for colposcopic evaluation and pathologic evaluation of specimens.
- ❖ Limited expertise in procuring equipment and materials from the United States, which has led to unexpected delays and additional expense.

Implications for Other Programs

The preliminary findings from this study are that:

- ❖ It is possible to achieve high participation in cervical cancer screening programs and necessary follow-up through personal attention to patients, flexible clinic schedules, and allocation of resources for follow-up. (Participation rates have been above 93 percent for all components of the study including interviews, exams, and biological sample collection.)
- ❖ Several new screening techniques are available, which may enhance the impact of cervical cancer prevention programs in developing countries. Until their cost is reduced, however, these new technologies may not be affordable to non-research programs.

More lessons will be available after the study is completed in 1998 and results are analyzed.

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Indonesia: evaluating alternative approaches to screening

Indonesia consists of more than 17,000 islands and has a population of nearly 180 million. This makes delivery of health services particularly challenging. In the late 1980s, pathology-based registry data suggested that cervical cancer was the most common cancer, accounting for nearly 20 to 25 percent of all malignancies reported. Although data are sketchy, an incidence rate of over 24 per 100,000 was reported in a population-based cancer registry at Semarang (Central Java).

While cytology-based screening has been available sporadically, primarily through private hospitals in urban areas, cervical cancer prevention services have not been organized or standardized as a comprehensive national effort and are generally not available outside of major urban centers. Key problems include insufficient incidence and prevalence data, poor training in Pap smear sampling, insufficient laboratory facilities and personnel to read Pap smears, lack of education among women about cervical cancer, and the high cost of services. In the early 1990s, the Indonesian Ministry of Health initiated a National Cancer Control Program in conjunction with the World Health Organization and other local nongovernmental organizations. Two organizations, in particular, have been working in collaboration with the Ministry of Health to improve cervical cancer prevention: the Indonesian Cancer Foundation (YKI) and Yayasan Kusuma Buana (YKB).

Program Description

Based in Jakarta, YKI has affiliates throughout the country and has undertaken efforts to create awareness about cervical cancer through education and screening campaigns and to promote early detection. Toward this end, YKI established an “Early Detection Center” in Jakarta, offering screening for cervical and other cancers, laboratory services, as well as palliative and hospice care. In addition, they have sponsored courses on cervical cancer screening for health providers and medical students. YKI also has been instrumental in establishing a nationwide pathology-based cancer registry in collaboration with the Ministry of Health and the Indonesian Society for Pathology. YKB comprises a network of eight integrated reproductive health clinics in low-income neighborhoods in Jakarta. These clinics offer family planning, maternal and child health, sexually transmitted disease, and Pap smear services, as well as counseling and community education on a variety of health issues. The clinics are staffed predominantly by nurse-midwives. YKB has been frequently at the vanguard of evaluating and introducing new reproductive health approaches and interventions.

Given the difficulties in undertaking Pap smear screening, especially in non-urban areas and among low-income populations, YKB, YKI, and the University of Indonesia, in collaboration with PATH, evaluated the acceptability and accuracy of using a low-power magnification device to enhance visual inspection of the cervix (compared to Pap smears). This approach, called Aided Visual Inspection (AVI), was evaluated in two phases among women aged 30-50: in the first phase, only YKI/University of Indonesia gynecologists used the device. During the second phase of the evaluation, YKB’s nurse-midwives were trained in AVI. Both phases indicated that this novel approach may hold promise in detecting high-grade dysplasia, either as an adjunct to

or replacement for cytology where health resources are limited. Investigators cited other benefits of this approach, including the ability to provide immediate feedback to the client, its low cost and ease of use, and its portability. Additional studies, however, are required to validate AVI.

Program Challenges

During the course of this research, several programmatic challenges existed, including:

- ❖ Loss to follow-up of some women identified with cervical abnormalities, apparently due to fear about the results and/or possible treatment.
- ❖ Inadequate quality control of cytology and limited colposcopic services for verification of results.
- ❖ Relatively high number of women presenting with late-stage cancer, especially at Jakarta's central hospital, where Phase I of the program took place.
- ❖ Minimal understanding among women about the nature of cervical cancer and its prevention.

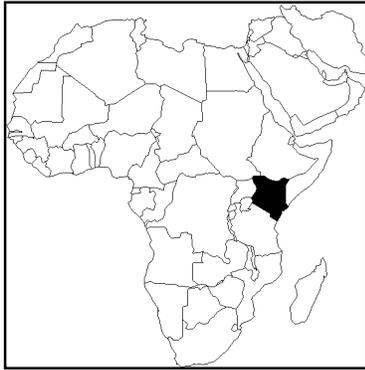
Implications for Other Programs

Despite the need for additional research, this project provided initial evidence that an alternative cervical cancer screening approach based on visual inspection may be feasible. In addition, this study, as well as YKB's ongoing cervical cancer prevention efforts, illustrate that non-physicians (in this case, nurse-midwives) can be trained to take Pap smears, as well as to use alternative screening approaches such as aided visual inspection. Finally, the efforts of both YKI and YKB illustrate the important role that nongovernmental organizations can play in supplementing governmental efforts to address health problems. Additional studies of visual inspection currently are planned or underway in other countries such as Zimbabwe and South Africa.

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Kenya: the Well-Woman Clinic project

The limited data available suggest that cervical cancer is a serious problem in Kenya. Hospital-based registries indicate that the disease accounted for 8-20 percent of all cancer cases from 1981-1990. At Kenyatta National Hospital in Nairobi, which has the country's only radiotherapy unit, over 500 cases are referred for treatment every year. Since many women are unable to travel to Nairobi from other parts of the country for diagnosis and treatment, this figure likely represents a very small proportion of the total number of women in need of care. In fact, limited research suggests

that over 600,000 women throughout Kenya may have cervical dysplasia, a significant portion of whom may have high-grade or severe dysplasia, thus requiring treatment to prevent cancer from developing.

Kenya does not have a comprehensive cervical cancer prevention program and few health facilities offer screening. Even fewer have diagnostic and treatment capabilities. Although some screening takes place in governmental family planning clinics, older women generally are not reached. Finally, public awareness of the disease is very low and few women request services.

Program Description

In 1992, the Kenya Medical Women's Association (KMWA) initiated the Well-Woman Clinic (WWC) in Nairobi, in collaboration with the Family Planning Association of Kenya (FPAK), to provide a variety of interventions to improve women's health. The first intervention to be introduced was cervical cancer screening. In 1994, KMWA established its own facility to support the expansion of cervical cancer and other services. A baseline study was conducted during the first phase of the project (May-December 1994) in which 520 women were screened. Of these women, about 15 percent had atypia, 29 percent had CIN I, 18 percent had CIN II, 10 percent had CIN III, and 1 percent were diagnosed with cancer.

Currently, KMWA's clinic offers cervical cancer screening; diagnostic and treatment services based on colposcopy, loop electrosurgical excision procedure, and cryotherapy; and a cytology laboratory to process smears. These services also are offered to other nongovernmental reproductive health clinics, with KMWA gynecologists and cytopathologists providing consultation, supervision, and quality control. Although some public education efforts have been undertaken, KMWA deliberately has not been very aggressive in this area due to concern that they might create a demand that neither the organization nor the country could meet at this time.

Because of the high rate of reproductive tract infections (RTIs) in Kenya, KMWA is assessing the feasibility of integrating RTI prevention and control and cervical cancer screening and management into existing governmental and nongovernmental health care structures. This evaluation first will seek to determine the prevalence of sexually transmitted diseases, HIV infection, and cervical dysplasia in one of the FPAK clinics. During the project's second phase, objectives include:

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- ❖ Pilot-testing a cervical cancer screening program, which reaches at least 50 percent of at-risk women in the Nairobi and Kisumu districts in the next five years.
 - ❖ Providing facilities for management of cervical dysplasia diagnosis and follow-up.
 - ❖ Establishing a feasible referral system for women diagnosed with cervical cancer.
 - ❖ Conducting research to determine appropriate strategies for integrating health care systems involved in reproductive health.

Program Challenges

Major barriers encountered by KMWA in establishing a cervical cancer control program include:

- ❖ The existence of a national health policy that does not directly address cervical cancer as a priority, which affects medical education of health care providers.
- ❖ Inadequate provision of equipment and supplies for screening in public health clinics.
- ❖ Lack of accurate incidence and prevalence data for planning.
- ❖ Misinformation about the disease on the part of women and providers.
- ❖ Poverty, which makes health care inaccessible to many women.

Implications for Other Programs

Although limited in scope, KMWA's efforts have been successful largely because of the following:

- ❖ Screening and treatment are kept affordable because KMWA members (gynecologists and pathologists) offer their consultation services for free.
- ❖ Referral of cancer cases to either public or private hospitals for management is arranged through the network of KMWA members working in these facilities. As a result, women who need follow-up receive it quickly and easily.
- ❖ Research activities have funded the training of KMWA gynecologists to perform colposcopy, as well as to become trainers themselves. Training for nurses in taking Pap smears also has been conducted.
- ❖ Functioning networks with other organizations to share resources, materials, and technical skills have allowed the program to reach more women.

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South Africa: cost-effectiveness study provides basis for strengthening a national screening campaign

Cervical cancer is the most common cancer among women in South Africa and accounts for about 25 percent of cancer deaths among black South African women. Death rates among women being treated for cervical cancer vary by race and geographic location. Though data are sketchy, data from Cape Town suggest that the peak incidence of dysplasia occurs among women in the 29-39 year age group. A cervical cancer

screening research project in Soweto (an urban township) revealed extremely high rates of CIN and invasive cancer in women aged 40-60, and unexpectedly high rates of dysplasia among teenagers.

South Africa has not had a great deal of success to date in implementing effective cervical cancer screening efforts. In the 1970s, the Department of Health advocated that Pap smears be done only if the cervix looked abnormal, a policy that was abandoned because, in general, by the time a clinician notices growths or discharge, cancer is already advanced. In the 1980s, the availability of Pap screening services was further curtailed as cervical cancer deaths were decreed not to be a serious problem compared with other health challenges. In 1989, a policy to screen women once in their lifetime at age 40 was initiated, but no coordinated mechanism to implement the policy was developed. Therefore, services remain variable. Although screening is theoretically available at Ob/Gyn, family planning, and ante- and post-natal clinics, little routine screening occurs in the public sector. In general, women have to initiate screening by requesting a Pap smear.

Program Description

As a first step toward developing a rational plan for promoting and implementing a national cervical cancer screening program, researchers from the Women's Health Project at the Center for Health Policy, Department of Community Health at the University of Witwatersrand Medical School in Johannesburg reviewed the cost-effectiveness of various screening assumptions, including screening interval. A summary of these findings was presented in a policy paper entitled *Toward a National Screening Policy for Cancer of the Cervix in South Africa*.

This document concludes that the current practice of opportunistic screening and treatment of precancerous and cancerous lesions is not a rational use of resources. A policy aimed at screening either 100 percent or 60 percent of all women over age 20 every five years would be *at least as cost-effective* as the current policy of treatment without an organized screening program. Another important finding is that use of specialists to perform Pap smears is not a practical or cost-effective approach.

The researchers recommend that a national screening program in South Africa be developed that calls for screening all women once in the next five years. The researchers acknowledge the need for more data on issues of cost, Pap smear quality, quality control of cytology laboratories, and outreach/education of at-risk women. They also recommend that pilot studies be run concurrently with a national screening program to evaluate those areas of concern.

The Women's Health Project proposes the following five points for the success of this program:

- ❖ Create consumer demand for Pap smears through education and publicity.
- ❖ Provide training for health personnel.
- ❖ Integrate routine Pap smear services into the national health service.
- ❖ Introduce a women's health card system with details of past screening dates and results and next screening date.
- ❖ Create a national database to track outcome of screening, diagnosis, and treatment.

Program Challenges

Some of the major challenges to developing a national screening program in South Africa that have been identified are:

- ❖ *Education of women:* Knowledge about Pap smears is very low nationally—any policy to increase screening should include an education program.
- ❖ *Integrating services:* Any planned screening program should be integrated into the existing clinic system.

Implications for Other Programs

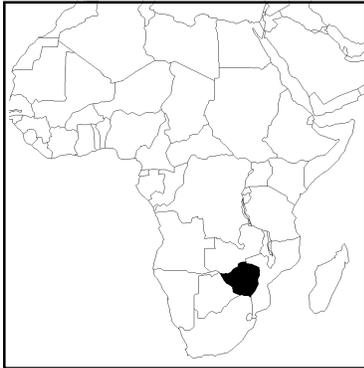
Some of the key recommendations to improve cervical cancer screening in South Africa are applicable to most programs working to improve cervical cancer control:

- ❖ Increase the number of women having Pap smears (coverage) rather than focusing on more frequent screenings.
- ❖ Develop effective quality-control systems in obtaining and interpreting Pap smears.
- ❖ Ensure appropriate follow-up of abnormal smears.
- ❖ Ensure that Pap smear services are effectively integrated into the existing health care infrastructure.
- ❖ Train providers to improve sensitivity toward client issues and concerns.

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(Based on Paper No. 31, published February 1993, ISBN No. 1-86838-049-1) *Towards a National Screening Policy for Cancer of the Cervix in South Africa*



Zimbabwe: study to estimate the sensitivity and specificity of UVI

In sub-Saharan Africa, cervical cancer is the most common female malignancy. There are notable regional differences in the prevalence of this disease, but the absence of cancer registries makes it very difficult to get accurate estimates of incidence rates. In a recent pilot study conducted in Zimbabwe among 1,000 rural women aged between 25-59, the prevalence of high grade squamous intraepithelial lesions was 5.6 percent.

Program Description

The University of Zimbabwe and the Johns Hopkins Program for International Education in Reproductive Health (JHPIEGO), in collaboration with the Commonwealth Regional Health Community for East, Central, and Southern Africa, are currently conducting a study to assess the effectiveness of unaided visual inspection (UVI) of the cervix. The study began in October 1996 and will involve 25,000 women aged 25 to 59.

Screening:

For this study, trained nurses provide all eligible women with UVI as well as a Pap smear. Any woman who has a positive result by either UVI or Pap smear receives a colposcopic exam. In addition, 10 percent of all UVI and Pap smear normal cases are examined by colposcopy. Biopsy is carried out as appropriate. A sample of Pap negative and all Pap positive smears are reviewed by cytopathologists not involved in the study as a means of quality control. Human papilloma virus (HPV) testing may be added to the study to assess the usefulness of HPV detection as a possible adjunct to UVI or cytology in screening and making treatment decisions.

Treatment:

Currently, colposcopy-confirmed cervical lesions are treated with loop electrosurgical excision procedure (LEEP), cone biopsy, or hysterectomy, depending upon the extent of the neoplasia and/or client preference. The study will measure comparative cure rates (at 12 months) between patients treated with LEEP and those treated with cryotherapy. The objective of this comparison will be to assess the extent to which cryotherapy can effectively be introduced as a "See and Treat" treatment option in Zimbabwe and similar settings.

Preliminary results:

Preliminary analyses of the pilot study suggest that UVI is as effective as cytology screening in the Zimbabwe study setting in detecting the presence or absence of cervical disease. Initial results based on colposcopic findings also suggest that disease rates in Zimbabwe are much higher than previously estimated and that younger women may be more affected by the disease than in other parts of the world.

Project Challenges

A pilot study, completed in September 1995, identified a number of clinical and study implementation issues:

- ❖ Tendency toward overdiagnosis among nurses using UVI.
- ❖ Tendency toward misdiagnosis of Pap smears among cytotechnicians due to lack of supplies and other cytology system-related problems.

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- ❖ Considerable loss to follow-up of women needing diagnosis due to problems getting to colposcopy clinics.
 - ❖ Backlogs in both Pap smear reading and colposcopy scheduling due to unanticipated high prevalence of disease.

These problems have been addressed in the ongoing main study through:

- ❖ Refresher UVI training for the nurses.
- ❖ Refresher cytology training for the cytotechnicians.
- ❖ Increased number of home visits by study nurses to reschedule missed colposcopy visits.
- ❖ Increased number of colposcopy clinics designated for study patients.
- ❖ Increased number of cytopathologists assigned to the study.

Implications for Other Programs

- ❖ The results of the main study, together with results from a recently conducted PATH-supported study in Indonesia (see page 4-7) and other similar studies, will provide evidence of the effectiveness and usefulness of visual inspection (aided or unaided) as an alternative (or adjunct) screening option to Pap smears. Decisions regarding which screening option is appropriate for which level of service delivery in any particular country must take into consideration many factors, including the prevalence of the disease, competing health priorities, treatment options available, local health care-seeking behavior, and supply and logistic constraints.
- ❖ To estimate the sensitivity and/or specificity of a particular screening or diagnostic tool, studies must ensure that a sufficient number of negative cases are assessed using the gold standard. Only in this way will the study have the required power to conclusively estimate these measures. For studies conducted under real field conditions, problems with loss to follow-up due to system overload (as a result of increased disease testing), in addition to the usual patient travel and time constraints, need to be realistically anticipated and accounted for when estimating required sample sizes and potential study bias.

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Introduction: Bibliography

This following abstracts represent selected studies, guidelines, and other documents relevant to providing cervical cancer control in low-resource settings. Some of the documents included in this bibliography are referred to in the fact sheets by author and date.

Bibliography

Abrams J

A preliminary study of the gynoscope: an adjunct to cytologic screening of the cervix

American Journal of Gynecologic Health, Volume IV, Number 1, pages 27-33, January/February 1990

The goal of this study was to determine whether cytology screening, which has a high false-negative rate, could be improved through use of a gynoscope. The gynoscope is a small, inexpensive, clip-on magnifying device that permits a clinician to differentiate more readily the varying degrees of white epithelium that may indicate dysplasia. After examining 309 patients in New Jersey, USA, the author compared two sets of laboratory results: results from examinations that combined gynoscope use with cytology and results from conventional cytology screening combined with occasional histology. The gynoscope false-negative rate of 12.6 percent compared well to the 15 to 40 percent false-negative rate that has been reported for cytology alone. The author concluded that use of the gynoscope as an adjunct to cytology screening may encourage better screening and a more confident discussion of findings by the clinician with patients and pathologists.

Andersen ES and Husth M

Cryosurgery for cervical intraepithelial neoplasia: 10-year follow-up

Gynecologic Oncology, Volume 45, pages 240-242, 1992

The goal of this study was to evaluate the long-term results of cryotherapy treatment of CIN. Some 261 patients in Denmark were evaluated over a 5-10 year period following cryotherapy. The authors reported an overall cure rate after 5 years of 83.5 percent. Consistent with findings elsewhere, the cure rates of patients with CIN III were significantly lower than those with CIN I and CIN II. Patients with endocervical involvement had lower cure rates as well. The authors concluded that this long-term study had demonstrated the effectiveness of cryotherapy, but cautioned that it also confirmed the need for other treatment methods for patients with endocervical involvement and for careful follow-up, given the risk of treatment failure.

Bishop A, Wells E, Sherris J, et al.

Cervical cancer: evolving prevention strategies for developing countries

Reproductive Health Matters, Number 6, pages 60-71, November 1995

This article makes a strong case for rational, public health approaches to the prevention and treatment of cervical cancer, focusing on practical strategies that can be used in developing countries. The authors note that scarce resources, limited infrastructure, and competing health priorities have prevented most developing-country health systems from implementing successful programs. Three approaches to cervical cancer screening are suggested for programs with limited resources: (1) screening women aged 30-35 or older; (2) screening women relatively infrequently; and (3) considering alternate approaches to conventional screening techniques. For women identified as needing treatment, the authors discuss outpatient approaches, such as cryotherapy and loop electrosurgical excision procedure (LEEP), that can effectively treat most precancerous lesions and reduce the number of clinic visits. The authors recommend coordinating efforts to achieve broader screening and treatment coverage, and they note that introducing alternate approaches requires policy changes, for which community input is essential.

Bishop A, Sherris J, Tsu VD

Cervical Dysplasia Treatment in Developing Countries: A Situation Analysis

PATH, Seattle, July 1995

This extensive review summarizes issues related to cervical dysplasia treatment in developing countries, including appropriate treatment strategies and technologies, a survey of current CIN treatment practices in developing countries, treatment costs analyses, and guidelines for establishing a treatment plan of action. Many of the useful tables and diagrams featured in this document are included in the Presentation Materials section.

Bosch FX, Manos MM, Munoz N, et al.

Prevalence of human papillomavirus in cervical cancer: a worldwide perspective

Journal of the National Cancer Institute, Volume 87, Number 11, pages 796-802, June 7, 1995

This study confirmed an extensive, global association between human papillomavirus (HPV) infection and cervical cancer. The study had two objectives: to determine whether the association between cervical cancer and HPV was consistent worldwide and to investigate geographic variation in the distribution of over 20 types of cancer-associated HPV. Investigators collected more than 1,000 specimens from cervical cancer patients in 22 countries with high recorded cervical cancer incidence. HPV DNA was detected in 93 percent of the tumors. Although HPV types differed somewhat by geographic region, HPV 16 was present in 50 percent of all specimens. The second most predominant type, HPV 18, was present in 14 percent of all specimens.

Brinton LA

Epidemiology of cervical cancer—an overview

In Muñoz N et al., eds. *The Epidemiology of Cervical Cancer and Human Papillomavirus*, International Agency for Research on Cancer, Lyon, Scientific Publication Number 119, pages 3-23, 1992

Numerous studies of cervical cancer epidemiology are reviewed in this 1992 publication that examines factors other than HPV associated with cervical cancer. In tables summarizing findings from multiple studies, the author demonstrates the strong association between cervical cancer risk and number of sexual partners and age at first intercourse (which may be markers for HPV risk). She then examines epidemiologic evidence for contributory or interactive roles of other suspected risk factors, such as the relationship between HPV and other sexually transmitted diseases. She reviews study findings for more speculative risk factors also, particularly cigarette smoking and use of oral contraceptives. She concludes by noting that disease risk may be affected by changes in recent times—including the tendency for women to initiate sexual intercourse at earlier ages, increased exposure by younger women to cigarette smoking and oral contraceptives, and changes in the sexual behavior of their male partners.

Burger RA, Monk BJ, Van Nostrand KM, et al.

Single-visit program for cervical cancer prevention in a high-risk population

Obstetrics and Gynecology, Volume 86, Number 4, Part 1, pages 491-498, October 1995

The three goals of this study were to screen and treat—in a single visit—women at increased risk for cervical cancer, to determine the feasibility of this single-visit approach, and to evaluate its acceptability to study participants. Some 126 women in southern California, USA, were recruited for the study through Spanish-language media; all had at least one risk factor for cervical cancer and most reported some barrier, usually cost, to obtaining health care. The single-visit program included a Pap smear; immediate cytologic evaluation; and, for those with cytology results consistent with low- or high-grade SIL, a loop electrosurgical excision or biopsy. Patients who underwent excision or biopsy were asked to return in two weeks for evaluation. The study found the See and Treat approach to be feasible and well accepted. Overtreatment (i.e., no histologic abnormality identified in the excised specimen) occurred in an estimated 5 percent of patients, a figure the authors deemed acceptable given the trade-off of convenient, effective, inexpensive care that does not rely on follow-up visits.

Eddy, DM

Secondary prevention of cancer: an overview

Bulletin of the World Health Organization, Volume 64, Number 3, pages 421-429, 1986

This document reviews evidence on the effectiveness of screening for eight cancers, and gives estimates of the potential impact of secondary prevention. Criteria for designing secondary prevention programs are listed, and the rationale for screening is discussed. The burden of disease associated with cervical cancer in developing countries is clearly described. The author estimated that, if launched in 1977, secondary prevention programs aimed at cervical cancer could have saved over 400,000 lives by the year 2000. Secondary prevention programs would have a much greater effect on cervical cancer mortality than on mortality associated with most other cancers.

Ho GY, Burk RD, Klein S, et al.

Persistent genital human papillomavirus infection as a risk factor for persistent cervical dysplasia

Journal of the National Cancer Institute, Volume 87, Number 18, pages 1365-1371, September 20, 1995

This study analyzed the factors that determine cervical intraepithelial neoplasia (CIN) persistence or regression and found that persistent CIN is linked to chronic HPV infection, particularly HPV infection with a high viral load. The study enrolled 100 U.S. women diagnosed with CIN II. About one-third of the women experienced regression; the remaining 70 were evaluated at three-month intervals for 15 months. Women who had continual HPV infection had a fourfold higher risk for persistent CIN than those without HPV. The authors noted that repeated testing for HPV infection may help clinicians to differentiate between women who are likely to experience spontaneous regression and women whose lesions will persist or progress.

IARC Working Group on Evaluation of Cervical Cancer Screening Programmes
Screening for squamous cervical cancer: duration of low risk after negative results of cervical cytology and its implication for screening policies

British Medical Journal, Volume 293, pages 659-664, September 13, 1986

This summary of an International Agency for Research on Cancer (IARC) assessment of cervical cancer screening programs in eight developed countries found little difference in the protection afforded by screening every year compared with every two or three years. Screening every five or ten years offered less protection, but may be appropriate in low-resource settings; even screening at ten years was associated with a reduced risk of nearly two-thirds. IARC noted that invasive cancer is extremely rare in women under 25; they recommended that screening programs focus on women aged 35-60. IARC stressed that ultimate effectiveness depends on proper clinical follow-up of abnormal cytological findings.

Keijser K, Kenemans P, van der Zanden P, et al.

Diathermy loop excision in the management of cervical intraepithelial neoplasia: diagnosis and treatment in one procedure

American Journal of Obstetrics and Gynecology, Volume 166, Number 4, pages 1281-1287, April 1992

This Dutch study found diathermy loop excision (another term for LEEP) to be an effective, efficient, and inexpensive technique for diagnosis and treatment of CIN. In the study, 424 women found to have slight to severe dysplasia (CIN grades 1-3) were treated with a stainless steel, rectangular loop used to excise lesions from the cervix and endocervical canal. Over a three- to eight-year follow-up period (median 4.8 years), the study found an overall cure rate of over 92 percent—81 percent after one treatment, the remaining 11 percent after two or three treatments. The authors characterized these results as in the same range with cryocoagulation and laser techniques, but noted that diathermy loop excision is an outpatient method, requiring no general anaesthesia and far less training and expensive equipment. They also found diathermy loop excision to be effective for treatment of lesions in the endocervical canal and calculated the method's diagnostic accuracy rate at 99 percent, with no evidence of an effect on fertility or pregnancy outcome.

Megevand E, Denny, L. Dehaeck K, et al.

Acetic acid visualization of the cervix: an alternative to cytologic screening

Obstetrics and Gynecology, Volume 88, Number 2, pages 383-386, September 1996

This study reports on results of an assessment of unaided visual screening of the cervix (after application of acetic acid) in a squatter area in Cape Town. Visual screening was offered through a mobile clinic, which also provided Pap smears, immediate colposcopy, and treatment as necessary. Over a seven-month period, almost 2,500 women attended the clinic. Of these women, 76 had "positive" visual inspections and 254 had positive cervical smears. While visual screening did not detect many low-grade dysplasias, it detected two-thirds of high-grade lesions; it also identified three cases of early stage invasive cancer. While the overall accuracy of visual screening could not be determined from the study, the authors concluded that unaided visual inspection warrants further consideration for use as an alternative to cytological screening in low-resource settings.

Miller AB

Cervical cancer screening programmes: managerial guidelines

World Health Organization, Geneva, 1992.

These guidelines outline management issues that must be considered when setting up a cytology screening program. After reviewing the natural history of cervical cancer, the guidelines detail strategies for: deciding whether to initiate cervical cancer screening; health service sectors through which screening can be offered; issues related to age of initiation and frequency of screening, health education needs; monitoring and evaluation needs; and other areas. The guidelines then provide specific strategies for providing cervical screening in primary health care settings and outline issues surrounding information systems for cervical screening, including the goals, characteristics, and data requirements of information systems. Lastly, the guidelines describe an approach to reducing cervical cancer mortality in countries where cytological screening cannot be provided. This approach, called downstaging, focuses on detecting early cancer when it is still treatable.

Murthy NS, Agarwal SS, Prabhakar AK, et al.

Estimation of reduction in life-time risk of cervical cancer through one life-time screening

Neoplasma, Volume 40, Number 4, pages 255-258, 1993

Given the recommendation by the World Health Organization (WHO) in 1986 that countries with limited resources should aim to screen every woman once in her lifetime, this study attempted to determine at what age that screening could cause the greatest overall reduction in mortality from cervical cancer. The study, using data from three cities in India, compared rates of cervical cancer incidence in unscreened women with incidence in women screened once in their lifetime at different ages (between ages 20 and 64). The authors found that screening at age 45 would be most effective, factoring in the number of cervical cancer cases prevented and the number of productive years of life saved.

Nasiell K, Roger V, Nasiell M

Behavior of mild cervical dysplasia during long-term follow-up

Obstetrics and Gynecology, Volume 67, Number 5, pages 665-669, May 1986

This Swedish study evaluated follow-up data from 555 women diagnosed with mild cervical dysplasia between 1962 and 1983. Of these mild dysplasias, 62 percent regressed, 22 percent persisted, and 16 percent progressed. Patients with regression were followed for an average of 39 months; patients with persistent dysplasia were followed for an average of 52 months. Where mild dysplasia progressed to more severe disease, the average time to progression was 48 months. Two cases of invasive cancer occurred in women lost to follow-up for several years during the study. The invasive cancers were diagnosed at 79 and 125 months after initial diagnosis of mild dysplasia. This study is often cited as evidence that a significant proportion of mild dysplasia does not progress to more severe disease. At the same time, the study results highlight the importance of regular follow-up of women diagnosed with mild dysplasia, given the potential of progression in more than a sixth of cases.

Olatunbosun OA, Okonofua FE, Ayangade SO

Outcome of cryosurgery for cervical intraepithelial neoplasia in a developing country

International Journal of Gynecology and Obstetrics, Volume 38, pages 305-310, 1992

In this Nigerian study, 73 women diagnosed with CIN were treated by cryosurgery. After a five-year follow-up period, the cure rate was 90 percent, excluding 22 women lost to follow-up. The authors characterized these results as comparable with those reported for other destructive methods and commended cryosurgery as a simple, low-cost, outpatient treatment approach, without serious side-effects or effects on pregnancy outcome. They emphasized, however, the importance of proper pretreatment evaluation and the need for long-term follow-up of patients. They also recommended against the use of cryosurgery for CIN with glandular involvement, given its limited depth of destruction.

Ottaviano M and La Torre P

Examining the cervix with the naked eye using acetic acid test

American Journal of Obstetrics and Gynecology, Volume 143, pages 139-142, May 15, 1982

This article reports on a study to compare examination of the cervix using acetic acid and the naked eye with use of colposcopy in identifying cervical abnormalities in 2,400 women. An atypical transformation zone was identified by visual inspection/acetic acid as white epithelium in 98.4 percent and as suspicious in an additional 1.6 percent of 312 colposcopically controlled cases. The authors conclude that the detection of intraepithelial or preclinical invasive cervical enoplasias need not depend on colposcopy. They caution, however, that colposcopy is essential in helping determine appropriate treatment options.

PAHO (Organizacion Panamericana de la Salud)

Cancer of the uterine cervix

Bulletin of the Pan American Health Organization (special issue), Volume 30, Number 4, December 1996 [Available in English and Spanish]

This special issue of the PAHO Bulletin includes 11 reviews and research articles on cervical cancer in the Latin American and Caribbean region. The articles include information on the epidemiology of cervical cancer in the region, the effectiveness of Pap testing in several countries, and women's knowledge and concerns about Pap testing in Chile and Mexico. Short communications on specific program activities and reports from the field also are included, as well as a list of recommended readings.

PAHO

Manual de normas y procedimientos para el control del cancer de cuello uterino

Organizacion Panamericana de la Salud, Serie PALTEX Para Ejecutores de Programas de Salud, No. 6, Washington, D.C., 1990

This Spanish language PAHO publication reviews all key managerial and technical aspects regarding cervical cancer control, with an emphasis on norms and procedures appropriate for the Latin American/Caribbean setting. The document includes the sections that describe: basic considerations for cervical cancer control, guidelines for cytological screening, diagnostic and treatment procedures, management of an effective program, and program monitoring and evaluation. The publication also includes several useful appendices which illustrate specific equipment and supply needs, evaluation indicators for cervical cancer control programs, and clinic and cytology registry forms.

Parkin DM, Pisani P, Ferlay J

Estimates of the worldwide incidence of eighteen major cancers in 1985

International Journal of Cancer, Volume 54, pages 594-606, 1993

As of 1996, this article was the most up-to-date source for the worldwide and regional incidence of cervical cancer. The authors report on International Agency for Research on Cancer data on estimated number of new cases, crude incidence rates, and age standardized incidence of 18 cancers, including cervical cancer. Data are provided for the developed and developing world, as well as for 24 specific regions.

Parkin DM

Screening for cervix cancer in developing countries

In Miller AB et al., ed. *Cancer Screening*, University Press, Cambridge, pages 184-198, 1991

This article analyzes findings from published studies of cervical cancer in terms of their implications for developing-country screening programs. Using data from multiple studies, the author estimates prevalence, relative risk, and age-specific incidence of cervical cancer. He notes that the possibility of different natural histories of disease in different parts of the world could have implications for the effectiveness of screening policies extrapolated from Western data. Key conclusions are that (1) increased frequency of screening yields a diminishing return in the number of cervical cancer cases prevented per 100,000 tests; (2) even low-intensity programs—with two to four tests per lifetime spaced out at ten-year intervals—can reduce the incidence of cervical cancer by 40-60 percent; (3) the focus of screening should be on reaching the entire population at risk rather than on frequent testing of population subgroups.

Ponten J, Adami H-O, Bergstrom R, et al.

Strategies for global control of cervical cancer

International Journal of Cancer, Volume 60, pages 1-26, 1995

This extensive review summarizes data from around the world on cervical cancer. Topics addressed include the tumor biology and natural history of cervical cancer, etiology of the disease (including impact of HPV), strategies for reducing mortality without screening (including focusing on treatment of early stage disease), and cytological screening. The authors concluded that the natural history and disease patterns of cervical cancer are similar throughout the world. They argued that HPV testing as a strategy for cervical cancer control remains experimental, and that providing treatment for early stage disease where feasible can help reduce mortality. They discussed the challenges of ensuring maximum coverage with cytological screening without wasting resources on frequent testing of women at lower risk.

Potosky AL, Annett DQ, Coyle L, et al.

Guide to Using CAN*TROL Version 2.0

National Cancer Institute, Division of Cancer Prevention and Control, Bethesda, MD, 1995

This document describes the CAN*TROL computer program, which can be used to model the effects of implementing various prevention, screening, and treatment interventions on cancer incidence, prevalence, and mortality as well as on cost effectiveness. For more information on the CAN*TROL program, contact Arnold Potosky, Ph.D., via E-mail at potosky@nih.gov or at the address below:

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Richard R

Screening: the next century

Cancer, Volume 76, pages 1919-1927, November 15, 1995

This article provides an excellent overview of existing and potentially new screening methods for application in both developing and developed countries. In addition to Pap smears, technologies reviewed for developing countries include unaided visual inspection with and without acetic acid (downstaging), aided visual inspection, and cervicography. Automated Pap machines and HPV DNA tests also are reviewed in the context of both high- and low-resource settings. The author addresses the effectiveness of various screening options as well as the likelihood that they will be available and cost-effective in high- and low-resource settings.

Richard RM and Wright TC

Controversies in the management of low-grade cervical intraepithelial neoplasia

Cancer, Volume 71, Number 4, pages 1413-1421, February 15, 1993

This article summarized contrasting views among U.S. physicians about treatment of low-grade CIN lesions—particularly (1) whether all patients with low-grade lesions require therapy and (2) what an appropriate role is for the loop electrosurgical excision procedure (LEEP) in cervical cancer treatment. The high remission rate associated with low-grade CIN lesions and the long time required for progression to cancer greatly supports a strategy of regular follow-up of the lesions rather than treatment. The authors cautioned, however, that surveillance instead of treatment for low-grade CIN lesions should be attempted only with patients able to return for regular follow-up. They also warned that no guidelines exist for length of follow-up periods, and that HPV typing (to determine which low-grade lesions will worsen or improve) is unreliable. The authors noted the value of LEEP in providing diagnosis and treatment of low-grade lesions within the same office visit. They also noted that LEEP critics express concern that it could cause overtreatment and excessive removal of cervical tissue.

Rogo KO, Omany J, Onyango JN, et al.

Carcinoma of the cervix in the African setting

International Journal of Gynecology and Obstetrics, Volume 33, pages 249-255, 1990

Data on 1,210 patients treated in Kenya between 1974 and 1979 formed the basis for this study. The authors compared Kenyan data to statistics for cervical cancer incidence in developed countries and found Kenyan patients to be both younger (mean age 42 versus 54 years) and more likely to present with late-stage disease (55 percent Stage 3 compared to 25 percent). A high loss to follow-up and limited treatment resources contributed to poor survival outcomes. The authors cited some possible additional contributors to high mortality, including tumor bulk, nutrition, and individual immunity. They concluded that further study of the differences in findings is needed and noted that cytologic screening is less likely to succeed in developing country settings.

Schiffman MH

New epidemiology of human papillomavirus infection and cervical neoplasia

Journal of the National Cancer Institute, Volume 87, Number 18, pages 1345-1347, September 20, 1995

This article discussed the link between persistent detection of HPV DNA (especially high levels of DNA) and persistent diagnosis of CIN. The author noted that Ho et al. (see above), which tracked HPV and CIN transience versus persistence, has implications for the development of screening strategies that include HPV DNA testing. The author noted several findings and factors that complicate epidemiologic analysis: (1) although it occurs in 10 percent or fewer cases, HPV-negative CIN does exist, (2) up to 10 percent of women may develop CIN II or III lesions initially instead of progressing from lower- to higher-grade lesions, (3) diagnostic ambiguities and the absence of a reference standard complicate interpretation of data, and (4) the cervix may contain discrete lesions with separate natural histories; for example, CIN I lesions may progress to CIN III over time or simply emerge adjacent to CIN III lesions.

Sherris JD, Wells ES, Tsu VD, et al.

Cervical Cancer in Developing Countries: A Situation Analysis

A World Bank Women's Health and Nutrition Working Paper, The World Bank, July 1993

This review summarizes a broad range of issues related to cervical cancer control in developing countries, including epidemiological and natural history issues, program experience to date, new screening and treatment technologies, and phased approaches to initiating a control programs in low-resource settings. Many of the useful tables and diagrams featured in this documents are included in the Presentation Materials section.

Sujathan K, Kannan S, Pillai KR, et al.

Implication of gynaecological abnormalities in pre-selection criteria for cervical screening: preliminary evaluation of 3,602 subjects in South India

Cytopathology, Volume 6, pages 75-87, 1995

This study evaluated correlations between Pap smear results and other factors, including age and gynecological complaints, to identify pre-selection criteria for cytological screening. Some 3,602 women voluntarily attending a cancer detection clinic in Kerala, South India, were included in the assessment. The authors concluded that cervical cancer control efforts in this setting should focus on women with the following characteristics: age over 40, married more than 20 years, and parity three or more. In accordance with previous Indian studies of visual inspection for detection of early cancer, the authors recommended that women with these characteristics should be referred for cytological screening if they have gynecological symptoms (bleeding, discharge, irregular menstrual periods, and others) or abnormal appearance of the cervix on visual inspection (without acetic acid).

Thomas DB, Ray RM, Pardthaisong T, et al.

Prostitution, condom use, and invasive squamous cell cervical cancer in Thailand

American Journal of Epidemiology, Volume 143, Number 8, pages 779-86, 1996

This article reports on a case-control study conducted in three hospitals to investigate the role of male sexual behavior in developing of cervical cancer in their wives. The study found that the rise of cervical cancer was strongly related to the women's husbands having visited prostitutes without using a condom when the husbands were less than 30 years old. The authors conclude that regular condom use by sex worker clients could reduce the number of invasive cervical cancer cases in Thailand's general population by at least 25 percent.

World Health Organization

Primary prevention of cervical cancer

World Health Organization, Geneva, October 3 -November 2, 1985 CAN/85.1

A WHO consulting group met in 1985 to consider possible approaches for primary prevention of cervical cancer. Given that cervical cancer is strongly linked to early onset of sexual activity and multiple sexual partners, the WHO group recommended sex education and studies in sexual behavior, while acknowledging that behavior is difficult to change. They recommended that development of vaccines for HPV be made a high priority, together with further study of the possible contribution of smoking to cervical cancer. They noted that there is no evidence to suggest a protective effect from hygiene, male circumcision, or nutrition, and that data are inconclusive on the role of oral or injectable contraceptives. They recommended that use of barrier methods, particularly condoms, should be encouraged.

World Health Organization

Control of cancer of the cervix uteri: review article based on a report of a WHO meeting, November 1985, Geneva

Bulletin of the World Health Organization, Volume 64, Number 4, pages 607-618, 1986

This article summarizes a WHO-sponsored meeting on cervical cancer convened in 1985. Meeting findings/highlights include: (1) risk of cervical cancer is closely linked to early onset of sexual activity, sexual experience with multiple partners, and HPV infection; (2) a 50-60 percent reduction in morbidity and mortality can be achieved through well-organized screening programs; (3) countries with limited resources should aim to screen every woman once in her lifetime between the ages of 35 and 40, and where more resources are available, the frequency of screening can be increased to once every 10, 5, or 3 years; (4) to broaden coverage, non-physician health workers can be trained to collect Pap smears; (5) organization, planning, training, and evaluation are critical to ensuring high-quality services; and (6) screening efforts should not exceed a level at which diagnosis and treatment resources become inadequate.

World Health Organization

Cytological screening in the control of cervical cancer: technical guidelines

World Health Organization, Geneva, 1988

These guidelines were designed to be used in conjunction with the WHO managerial guidelines abstracted above (Miller 1992). After a general introduction to the problem of cervical cancer and the role of cervical cytology in cervical cancer control, the guidelines provided detailed information on collection of cervical smears; cytology laboratory processes; diagnostic, treatment, and follow-up procedures; monitoring and evaluation issues; and personnel, equipment, and supply needs. One section of the guidelines also outlines common faults of screening programs and suggested solutions.

World Health Organization

Cancer pain relief and palliative care: report of a WHO expert committee

World Health Organization, Technical Report Series 804, Geneva, 1990

This report summarizes the findings of a meeting of the *WHO Expert Committee on Cancer Pain Relief and Active Supportive Care*. The report reviews the principles of palliative care, including obstacles to implementing effective palliative care. It defines the type of pain associated with cancer, as well as other symptoms associated with advanced cancer, and describes the drugs used to treat cancer pain. The report emphasizes that palliative care must encompass the psychosocial and spiritual needs of cancer patients and discusses ethical issues that providers may need to consider when working with terminally ill people. Lastly, the report lists key program issues that must be considered before implementing palliative care (including education and training needs) and includes recommendations to WHO and WHO member-states on key strategies for making palliative care accessible to those who need it.

World Health Organization

Cancer Pain Relief, 2nd Edition [with a guide to opioid availability]

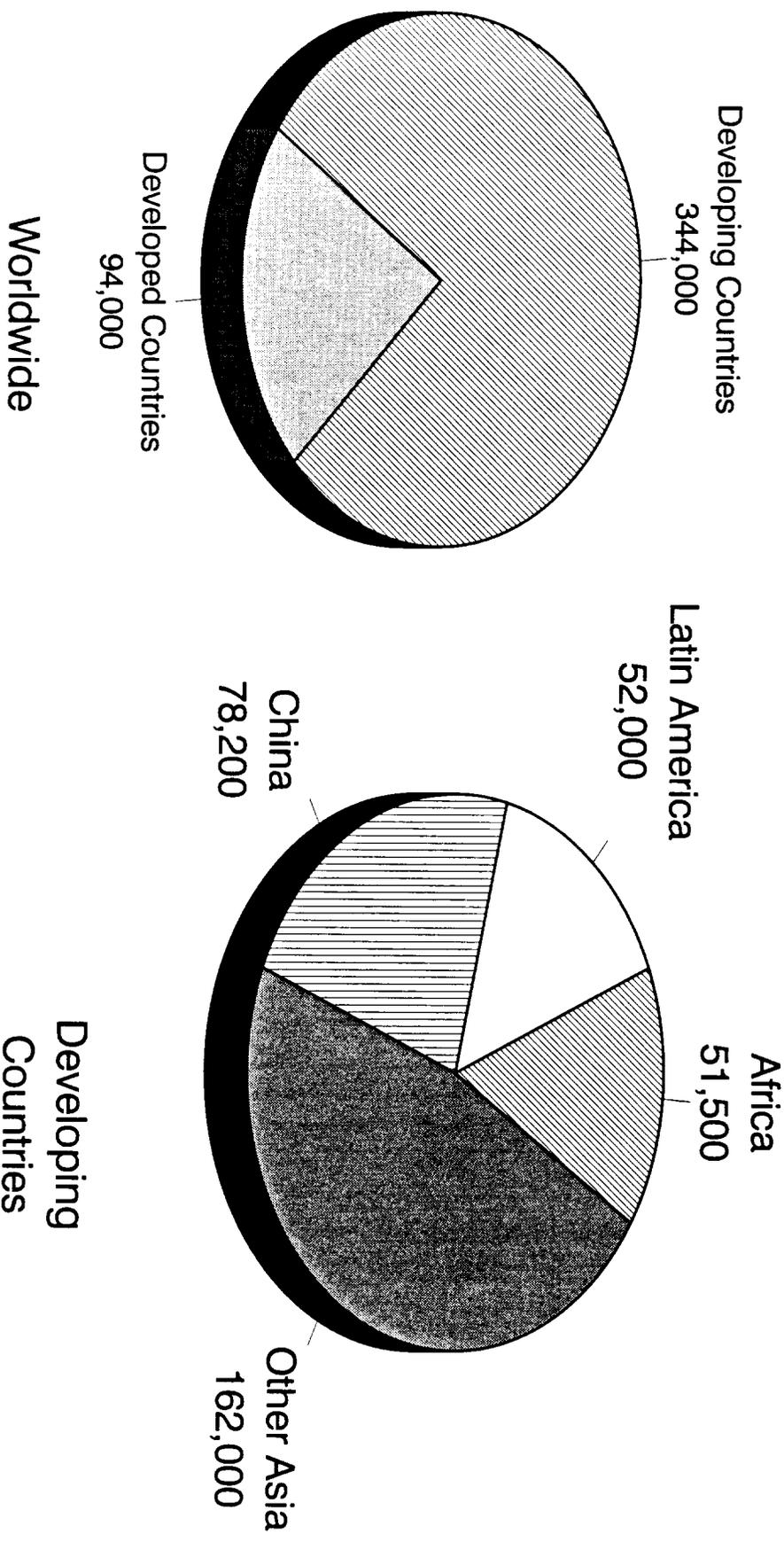
World Health Organization, Geneva, 1996

This document updates the 1990 WHO report summarized above. In particular, opioid availability is addressed, including strategies for overcoming barriers to obtaining a regular supply of opioids.

Introduction: Presentation Materials

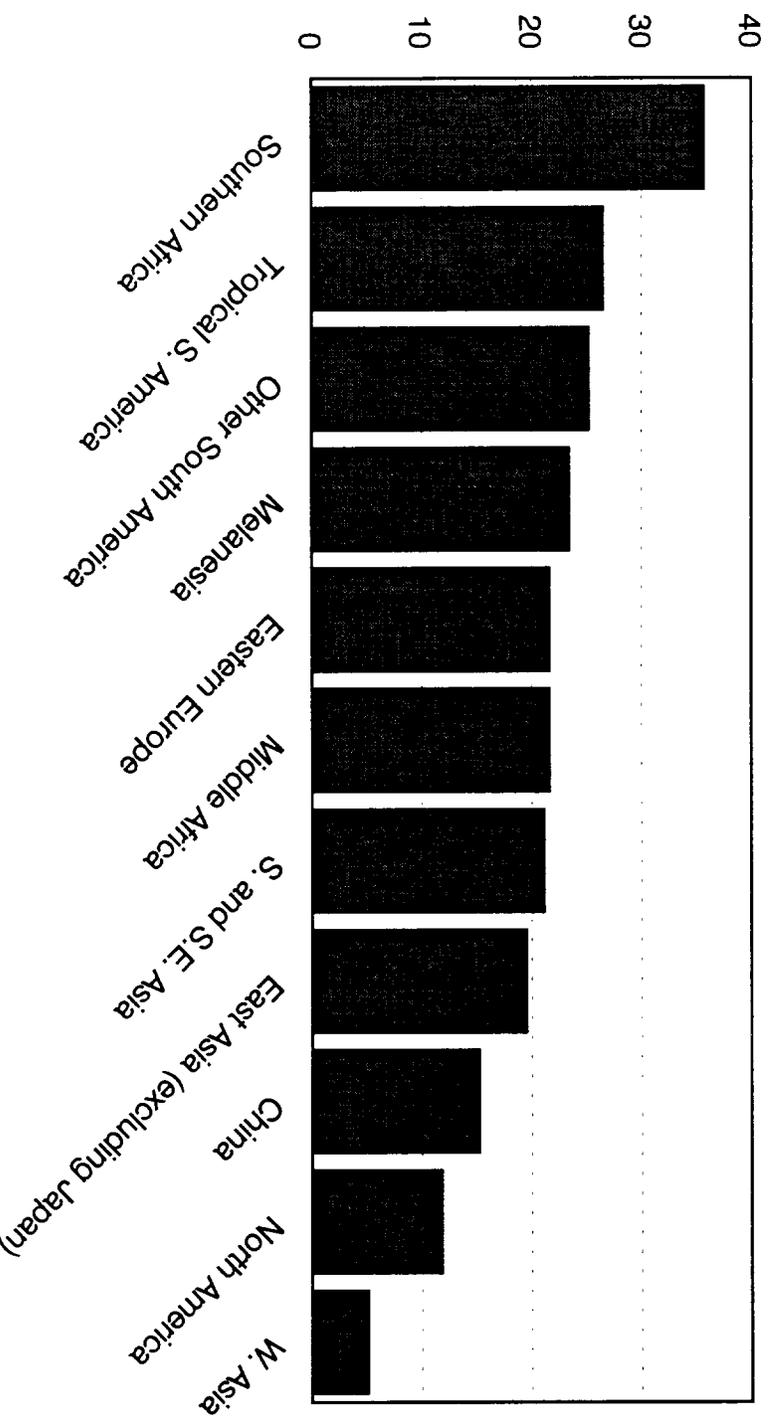
This section includes a selection of charts, tables, and other graphic materials that can be used as illustrations for documents or presentations about cervical cancer. These materials can be duplicated or made into overhead transparencies or slides without permission. If you have other presentation materials on cervical cancer, please send them to PATH if you would like them included in future editions of this document.

Estimated Number of New Cervical Cancer Cases Per Year, 1985

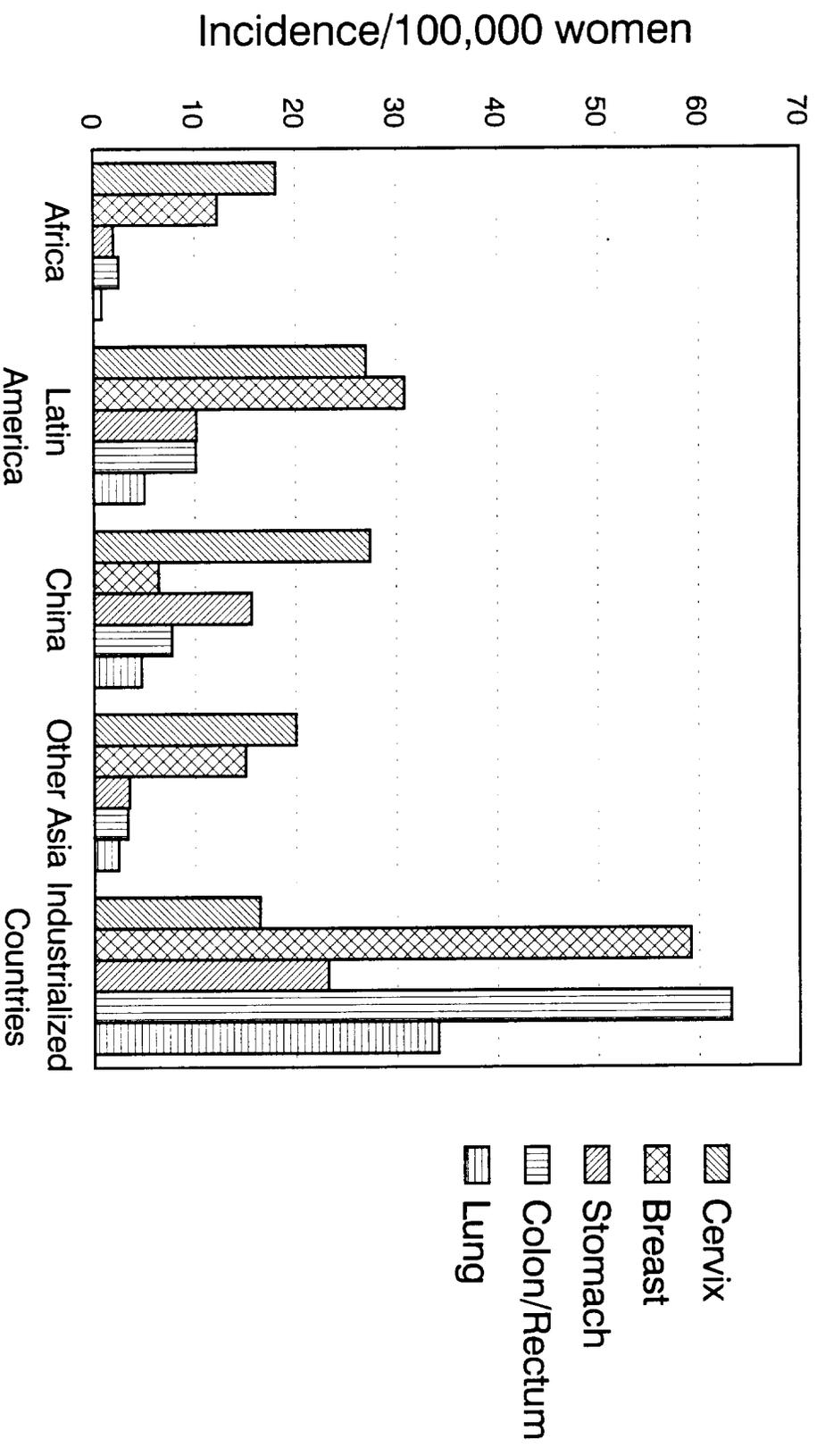


Estimated Minimum Incidence of Cervical Cancer by Region, 1985

(rate per 100,000 women)



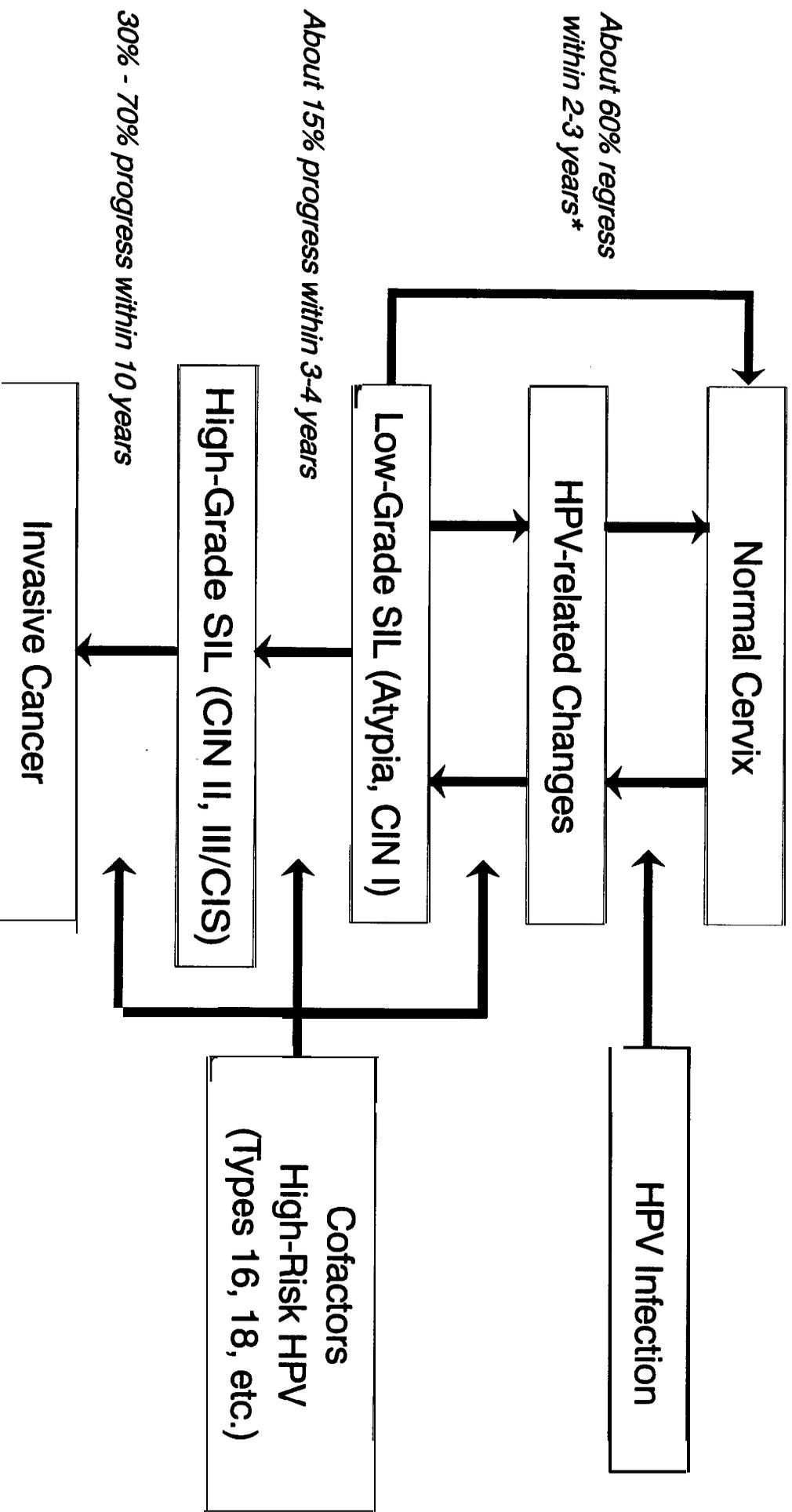
Estimated Crude Incidence Rates of Selected Cancers by Region, Early 1980s



path/1997 - Source: Adapted from Barnham and Greenberg, in Jamison et al., 1993

Natural History of Cervical Cancer

Current Understanding



*NOTE: Prevalent cases will have a lower regression rate

Factors Limiting the Impact of Developing Country Screening Programs

- Low overall coverage rate
- Failure to reach high-risk women
- Unavailable or unreliable cytology services
- Inadequate provider training
- Shortage of basic supplies
- Inadequate treatment services
- High cost of services
- Difficulty in client follow-up
- Low awareness of cervical cancer as health problem

Reduction in Cumulative Cervical Cancer Rate with Different Frequencies of Screening

Frequency of screening*	% reduction in cumulative rate
1 year	93.5
2 years	92.5
3 years	90.8
5 years	83.6
10 years	64.1

*Screening all women age 35-64 who have had at least one previous negative screen

Two Screening Strategies in Chile

	Program 1	Program 2
Age	30-55 years	30-50 years
Screening frequency	3-yearly	10-yearly
Coverage	30%	90%
Mortality reduction	15%	44%
Cost per case detected	US\$2,522	US\$556

path/1997 - Source: Eddy, 1986, as described in Miller, 1992

Other Proposed Approaches to Cervical Cancer Prevention in Low Resource Settings

	Effective	Safe	Practical	Affordable	Available
Visual Screening: Aided	?	Yes	Yes	Yes	Yes
Visual Screening: Unaided	?	Yes	Yes	Yes	Yes
Automated Pap Screening	Yes?	Yes	?	No	No
HPV Screening	?	Yes	?	?	Yes
Cervicography	Yes?	Yes	?	?	Yes
HPV Vaccine	?	?	Yes	?	No

Treatment Options for Dysplasia/CIS

	Cryotherapy	Diathermy Loop Excision (LEEP)
Effectiveness	80%-90%	90%-95%
Side Effects	watery discharge infection risk	bleeding
Anesthesia Required	no	yes
Tissue Sample	no	yes
Power Required	no	yes
Cost	relatively low	relatively high

Cost-effectiveness of Cervical Cancer Screening and Other Health Interventions

Intervention	Cost per DALY* (US\$)
Smoking cessation programs	20
Polio vaccination	20-40
STD management	1-55
Cervical cancer screening	100
Integrated antenatal/delivery care	30-250
Malaria treatment	200-500
Cervical cancer treatment/palliative care	2600

*DALY = disability-adjusted life-year gained

Enhancing Cost-Effectiveness of Cervical Cancer Screening

- Screening less frequently
- Targeting older women, high-risk populations
- Improving accuracy of screening test
- Reducing cost of screening test
- Using less expensive treatment strategies
- Integrating services with other health programs

Recommendations for Targeted Cervical Cancer Research

- Collect and analyze incidence and prevalence data
- Investigate cost implications of using simple treatment technologies
- Evaluate feasibility of visual screening approaches
- Evaluate women's understanding of cervical cancer
- Investigate appropriate ways to reach at-risk women
- Gather cervical samples for HPV testing
- Assess physicians' views of new screening and treatment approaches

Loop Excision

Advantages

- Effective for all CIN lesions (90%-96% cure rate)
- Simple to use
- Tissue sampling and treatment in 1 visit
- Few complications

Disadvantages

- More expensive than cryotherapy (\$4,000-\$6,000)
- Bleeding
- Requires electricity
- Requires local anesthesia
- Requires resupply of loops

Cryotherapy

Advantages

- Effective for mild to moderate CIN lesions (90%-95% cure rate)
- Inexpensive (\$1,000-\$3,000)
- Simple to use
- No anesthesia required
- No electricity required

Disadvantages

- Less effective for large, severe lesions
- Destructive method: no tissue sample
- Profuse, watery discharge
- Risk of cervical stenosis, infection
- Requires refrigerant

Minimum Cervical Cancer Program Goals

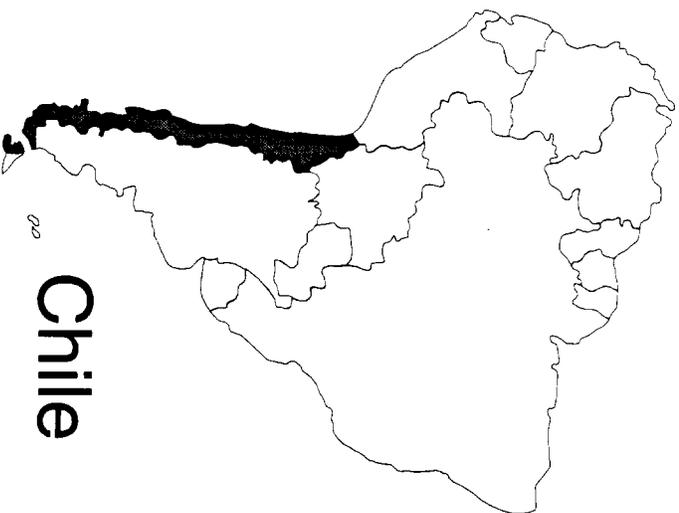
- Information, education, and communication
 - Increase awareness of cervical cancer and available health services among women aged 35 to 50
- Screening
 - Screen women at least once between the ages of 35-50
- Diagnosis and treatment
 - Treat women with high-grade dysplasia, refer those with invasive disease where possible, and provide palliative care for women with advanced cancer
- Monitoring and evaluation
 - Collect service delivery statistics that will facilitate ongoing monitoring and evaluation of program activities and outputs

Increasing Cervical Cancer Awareness Among Women \geq 35

Involve women to determine most appropriate strategies

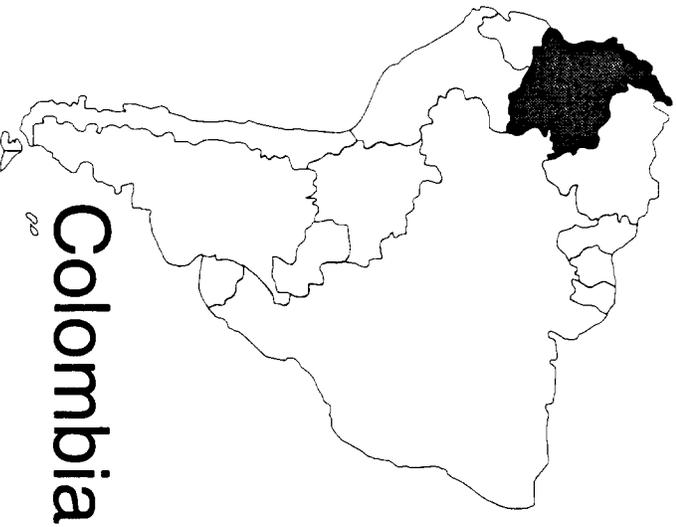
Possible approaches:

- **Use established communication structures such as mass media**
- **Use local women's or community groups**
- **Link screening to other midlife health needs or important events**
- **Reach women through husbands or children**



Chile

"Success breeds success. Better coordination and guidelines, improved quality control, and more focused screening have helped the program optimize resources and become successful. As the program has shown improved results, the government has been more willing to provide administrative and financial support."



Colombia

"Bottlenecks to program implementation should be identified at the start. In the Colombian program, the shortage of cytotechnicians was a key barrier to meeting program needs. In addition, the growing demand from women asking for Pap smears put pressure on the system to train more cytologists."



Colombia

"It is crucial to develop an effective information system that allows for regular evaluation of program activities and achievements. This evaluation allows for identification of both program successes and program activities that need to be improved."