



**Workshop Highlights:  
Alternatives for  
Cervical Cancer Screening  
and Treatment in  
Low-Resource Settings**

**21-22 May 1997**

JHPIEGO, an affiliate of Johns Hopkins University, is a nonprofit corporation dedicated to improving the health of women and families throughout the world. JHPIEGO works to increase the number of qualified health professionals trained in modern reproductive healthcare, especially family planning.

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# Introduction

Each year since 1994, in conjunction with its annual Board of Trustees meeting, JHPIEGO has convened a workshop that deals with a reproductive health topic in which training plays an important role. This year's workshop was held on 21 and 22 May 1997 and dealt with cancer of the cervix, the same reproductive health topic that JHPIEGO's first Board of Trustees workshop focused on in 1994. Whereas the 1994 workshop reviewed the status of cervical cancer screening worldwide and discussed alternative methods of detecting cervical cancer, this year's presentations discussed screening *and* treatment options, specifically focusing on alternatives for low resource settings. Workshop participants included JHPIEGO's international board members plus a select group of health professionals involved in cervical cancer programs worldwide.

The issue of *whether* cancer of the cervix is a public health problem meriting attention by national health programs as well as donor and development assistance organizations was not discussed at length in this workshop. Rather, the workshop was dedicated to identifying approaches that could be used to address cervical cancer in settings where this disease *has been* identified as a public health priority. To accomplish this, participants were first updated on the scientific evidence available that supports various cervical cancer screening and treatment options. These updates were followed by reports on and discussions of country experiences with cervical cancer screening and treatment programs and field perspectives on these types of programs in a number of developing countries.

## Workshop Objectives

- Reach consensus on the appropriateness of visual inspection as an alternative cervical cancer screening technique
- Review the usefulness of a see and treat approach for managing pre-invasive cervical disease
- Identify issues related to the *introduction* of alternative screening and treatment approaches for pre-invasive cervical disease in low-resource settings
- Identify approaches for integrating competency-based training on the management of pre-invasive cervical disease into reproductive health training

# Key Issues

## Introduction

Given the scope of the cervical cancer problem in developing countries, coupled with the difficulties that have been encountered in many of these countries when attempting to implement cytology-based screening programs, this workshop focused on alternative, low-resource screening options—some of which have been available for decades. Major workshop themes included the importance of assessing the cost effectiveness of currently used cervical cancer screening and treatment methods and finding ways to overcome barriers to implementing successful screening programs in developing countries. Workshop participants were given an opportunity to examine cytology based screening—the current screening *standard* worldwide—and consider its clinical effectiveness and programmatic limitations. They also were provided a historical review of research on visual inspection for cervical cancer screening—including updates on recently completed and ongoing studies. This review enhanced the participants' ability to consider the potential role of visual inspection as an alternative to cytology for cervical cancer screening in low-resource settings.

Following a consideration of cervical cancer *screening* alternatives, cervical cancer *treatment* options were discussed. This involved a review of the efficacy of loop electrosurgical excision procedure (LEEP) and cryotherapy as well as the feasibility of using these treatment options in low resource settings.

Several additional themes were also considered that are particularly relevant in many developing countries where resources are scarce. For example, the problem of loss-to followup (i.e., women not returning for followup diagnostic tests and treatment) is a major barrier to the success of screening and treatment programs in many developing country settings. The “see and treat” approach—in which treatment, if needed, is offered immediately after screening during a single visit—was introduced as a possible solution to this problem. Participants examined this option as it relates to the issue of overtreatment and how this affects healthcare systems and individuals within those systems.

## Scope of the Problem

Cervical cancer is the most common cancer and the leading cause of cancer death among women in developing countries. It is estimated that 200,000 to 300,000 women die from cervical cancer every year, mostly in poorer countries (Franco and Monsonogo 1997, Parkin, Pisani and Ferlay 1993). Even more sobering are findings from recent studies which suggest that human immunodeficiency virus (HIV)-positive women are at *increased* risk for cervical cancer (Judson 1992), and HIV rates are known to be on the increase in many of the same countries in which cervical cancer is a leading cause of cancer deaths. Thus, it is very likely that deaths due to cervical cancer will increase in these countries in the coming years. *Death resulting from cervical cancer is particularly tragic because this type of cancer develops slowly and has a detectable precursor condition, carcinoma in situ (CIS), which is treatable.*

### **Primary [and Secondary] Prevention of Cervical Cancer in ECSA**

“Cervical cancer is the most common malignancy among women in East, Central and Southern Africa (ECSA) Yet it is a preventable and treatable disease whose primary prevention could be achieved through prevention and treatment of sexually transmitted diseases, and institution of low cost screening programs (such as visual inspection of the cervix) to detect treatable precancerous conditions of the cervix

The Commonwealth Regional Health Community Secretariat (CRHCS) ECSA views cervical cancer as an important public health problem whose prevention should be integrated in all existing primary healthcare and women’s health programs in the region ”

Winnie Mpanju-Shumbusho, MD, MPH, MMED, CRHCS, Arusha, Tanzania  
JHPIEGO Board of Trustees Workshop, 21–22 May 1997

## **Screening**

### **Cost-Effectiveness of Cervical Cancer Screening**

A study funded by the World Bank supports the claim that cervical cancer screening is not only of value in terms of lives saved but also that it is a *cost effective* public health intervention (Jamison et al 1993) In that study, the cost per disability-adjusted life year (DALY)<sup>1</sup> gained for cervical cancer screening (assuming screening for all women every 5 years) is about \$100<sup>2</sup> This compares favorably to other preventive health interventions (e g , \$30 to \$250 per DALY for antenatal/delivery care, \$15 to \$75 for increased condom use, \$30 to \$150 for IUD services) and is a fraction of the estimated cost (\$2,600) for treatment/palliative care for cervical cancer (Program for Appropriate Technology in Health [PATH] 1997) It is reasonable to assume that in many settings the cost-effectiveness of cervical cancer screening could be increased even further if there were greater coverage of high-risk women, screened at intervals greater than 5 years, and if less expensive outpatient therapeutic approaches were used to treat cervical lesions

### **Cytology-Based Screening**

In 1989, the pathologist Leo Koss observed that “there has been no objective statistical analysis of the optimal performance of [the cervical smear]” (Koss 1989) In fact, the Papanicolaou (“Pap”) smear is one of a unique group of tests that have been widely adopted into standard (western) clinical practice without first being subjected to rigorous, prospective blinded studies to examine their effectiveness (Franco and Monsonogo 1997) Regardless, over time, the Pap test has proven to be a clinically useful tool, and both clinicians and researchers alike claim it has played an important role in cancer reduction

In developed countries, cytology-based services utilizing the Pap smear have been the basis of cervical cancer screening and detection programs for many years While some data suggest that cervical cancer rates began to decrease before large-scale Pap smear screening programs were introduced (perhaps in association with the reduction in parity that has occurred since World War II), it is generally accepted that the initiation of such national screening programs is largely responsible for, or at least has contributed in a significant manner to, the marked decline in cervical cancer deaths in those countries in the ensuing years Decreases in the incidence rates of cervical cancer have occurred in Finland, Iceland and Sweden, where national population-based programs have been in operation at least since the early 1970s In Finland, a 65% reduction in the incidence rates of cervical cancer was observed between 1966–1970 and 1981–1985 By

contrast, in Norway, where only 5% of the population was covered by a cervical cancer screening program, the reduction in cervical cancer incidence was only 20% during this same 15-year period. These findings indicate a strong correlation between the *extent* (coverage) of a screening program and the reduced incidence of invasive cervical cancer (Franco and Monsonogo 1997)

### **Limitations of Cervical Cancer Screening in Developing Countries**

In most developing countries, only 5% of women at any point in time have been screened within the past 5 years (WHO 1986). If the burden of disease is high and screening is known to be a cost-effective intervention, why isn't screening more prevalent in most developing countries? One reason relates to the nature of the Pap smear, the most common form of screening performed worldwide. Cytology-based screening programs are complex and can be costly. Although performing a Pap test may seem relatively simple, from both a clinical and programmatic perspective, a large number of steps are required to take an adequate smear, process and analyze the specimen, and inform patients of the results. If any of these steps are unreliable or logistically burdensome, the entire screening program could break down and, with it, the potential for any public health benefit.

Unfortunately, many, if not all, of these steps can be problematic in many developing countries. For example, whatever cytology screening services that *do* exist in such resource-limited settings are usually offered only in urban settings by a small private sector or at referral facilities. And, even in these settings, trained cytotechnicians and cytopathologists are scarce and turnaround times for processing and reading specimens are slow. Thus, patients do not receive their results promptly and followup losses (including patients lost to treatment) are high. Given this reality, if screening (and subsequent treatment) is to have a measurable effect on the burden of disease borne by women and the healthcare system, it is apparent that cervical cancer screening based on an approach other than just Pap smears is needed.

### **History of Research on Visual Inspection**

Historically, before the advent of Pap smears and programmatic screening, healthcare providers relied on looking at the cervix to detect abnormalities. For example, the Schiller test (i.e., application of dilute aqueous iodine solution to the cervix to aid in differentiating "mature" normal from "immature" abnormal epithelium) has been used for many years.

After the 1950s, when the Pap smear became the standard for cervical cancer screening, increasing numbers of women undergoing this test led to increased utilization of the colposcope (initially developed in the 1930s) to *confirm* screening findings. Years later, given the expense and inconvenience of colposcopy services, clinicians began to explore whether unmagnified visualization of the cervix (with acetic acid) could be used as an *adjunct* to cytology so that patients in need of colposcopy could be identified more effectively and efficiently. Few studies were conducted, however, that examined the value of unmagnified inspection of the cervix after the application of acetic acid for purposes of identifying a normal "transformation zone" or detecting precancerous lesions of the cervix (i.e., primary screening).

Then, in 1982, Ottaviano and La Torre published an important study involving 2,400 women who were examined visually and colposcopically after a cervical wash with acetic acid. A key result was that "naked eye" (unmagnified) inspection detected abnormalities in 98.4% of the cases (i.e., in 307 of 312 patients assessed colposcopically as having an abnormal transformation zone). In addition, (unmagnified) visual inspection with acetic acid (VIA) identified 98.9% of the cases as normal (i.e., in 1,568 of 1,584 women diagnosed as normal by colposcopy). **These authors concluded that "colposcopic magnification is not**

essential in clinical practice for the identification of the cervix ‘at risk’” (Ottaviano and La Torre 1982)

Subsequently, in 1990, Abrams published his experience with the “Gynoscope,” a monocular telescope with a magnifying power of 2.5, which he developed as an adjunct to cytological screening (Abrams 1990). In that study, Abrams reported a high correlation between the (visual) Gynoscope examination and cytology (supplemented by biopsy results in a few cases).<sup>3</sup> His findings suggested that the use of a low-power device could provide excellent results as an adjunct to cytology and **“should be considered as a practical adjunct that will encourage better sampling by the clinician [and] alert the pathologist to the presence of a suspicious lesion ”**

Two more recent studies also demonstrated that visual inspection of the cervix can be helpful in reducing referrals for colposcopy without compromising quality of care (Frisch, Milner and Ferris 1994, Slawson, Bennett and Herman 1992). For example, Slawson et al found that among women who eventually had an abnormal biopsy, VIA detected disease in approximately 64% of such cases, a very similar rate to what they found for the Pap smear (68%). In addition, as the investigator became more experienced, positive predictive value improved by almost 30%. Thus they concluded that **“[VIA] is a safe, simple and effective adjunct to the Papanicolaou smear for cervical cancer screening ”** Likewise, Frisch et al discovered that using VIA as an adjunct to cytology improved both the number of dysplastic lesions found as well as the negative predictive value of cytology (that is, if the Pap smear and the visual inspection *both* were normal, colposcopy and biopsy were also more likely to be normal than if *just* a Pap smear was performed).

### Visual Inspection as an Alternative to Cytology in Low-Resource Settings

“The issue is not to what should we compare visual inspection. We have nothing now that is accessible to the majority of women in our region and visual inspection would at least give us something.”

Robert J. Leke, Professor, University of Yaoundé, Faculty of Medicine and Biomedical Sciences, Cameroon  
JHPIEGO Board of Trustees Workshop, 21–22 May 1997

Even though the studies described above all contributed to demonstrating the *potential* value of visual inspection of the cervix as a screening approach, evidence from more rigorous scientific studies was needed before clinicians would accept visual inspection as an alternative to cytology as a *primary* screening approach—even in settings where Pap smear based services are not possible (Franco and Monsonego 1997).

To this end, the World Health Organization (WHO) supported a study in India between 1988 and 1991 in which unmagnified visual inspection with acetic acid washing was evaluated as a “downstaging” technique.<sup>4</sup> The results of this study showed VIA to be effective in identifying women with *cancer* at an earlier, more treatable stage (Singh, Sehgal and Luthra 1992). In 1994 another study was conducted in South Africa involving visual screening and Pap smears, performed in a mobile unit equipped to process smears on site. A gynecologist performed colposcopy to confirm disease in the mobile unit either immediately or within a couple of days after screening. The positive predictive value for VIA was found in this investigation to be similar to that of the Pap smear and the authors thus concluded that **“naked-eye visualization of the cervix after application of diluted acetic acid warrants consideration as an alternative to cytologic screening”** (Megevand et al 1996). Finally, in a recent 1997 publication, Franco and Monsonego described their experiences with women who had reported to an early cancer detection center in India for opportunistic cervical cytology and agreed to participate in a study to evaluate unaided

visual inspection, cervicoscopy and cytology (Franco and Monsonogo 1997) Preliminary results of this study indicated that, compared to cytology, VIA was more sensitive in detecting lesions although the difference was not statistically significant In this study, however, the specificity of cytology was statistically significantly higher than that of VIA

Finally, the findings or preliminary results of four recent or ongoing studies on visual inspection in Indonesia, Kenya, Zimbabwe and South Africa<sup>5</sup> provide supportive additional information These studies seek to answer the basic research question “What are the test qualities of visual inspection as a primary screening modality?” Most of these studies also address the more specific question of whether visual inspection is “acceptably” effective in distinguishing diseased from nondiseased persons in a particular healthcare setting by comparing the test qualities of visual inspection with other screening tests (e g , Pap smears) performed under the same conditions While it is too early to draw conclusions from ongoing studies, **preliminary or final results from the comparative studies suggest that visual inspection with acetic acid performs comparably to the Pap smear and/or other screening tests being investigated in those settings** Once the two ongoing studies are completed, these results should provide the additional evidence needed to support clinicians in their decisions regarding the use of visual inspection as a primary screening approach

## **Treatment**

### **Efficacy of Cryotherapy and Loop Electrosurgical Excision Procedure**

For cervical cancer screening programs to be effective and ethical, appropriate treatment must be both available and affordable to those who test positive for disease The treatment options generally suggested for precancerous lesions are cryotherapy and LEEP A situation analysis report describing the comparative advantages and disadvantages of treatment options noted that the effectiveness of both methods (as revealed in numerous research studies) is high, 80–95% (Bishop, Sherris and Tsu 1995)

The results of a survey of therapies currently used in developing countries to manage cervical intraepithelial neoplasia (CIN) are also reported in the situation analysis document The survey revealed that hysterectomy and cone biopsy—both of which involve hospital stays and are associated with significant procedure-related costs and risks—are commonly used methods, despite available scientific evidence that supports both LEEP and cryotherapy as effective outpatient treatment modalities The use of methods that are more costly and potentially more risky to the patient (e g , hysterectomy) is due in part to a tendency towards medicalization of healthcare and also to the fact that in some countries screening is not routinely offered at levels of the health system where outpatient treatment such as LEEP and cryotherapy could be made available

### **Managing Precancerous Disease**

The recommended management approach is based on the principle that screening and treatment can take place during the same visit and, further, that screening and immediate treatment can take place at the lowest possible level of the health system (where the majority of at risk women will go at least once in their lives) Given that the healthcare provider most often posted to such levels is a nurse or nurse midwife, this approach assumes that both screening and treatment can be performed competently by these or similar cadres of health personnel A major advantage of managing precancerous disease using this approach is that it offers a potential solution to the problem of loss-to-followup that occurs as a

consequence of the need to wait for cytology based screening results (Pap smear processing and return of results) as well as the need, which often occurs, to go to a different facility for treatment

### **Treating Women with Unconfirmed Disease**

Results reported to date pertaining to the specificity of visual inspection from test quality studies suggest that providers might *offer* treatment to a number of women when, in fact, no disease is clinically detectable. In turn, a significant number of these women might decide to be treated. This “overtreatment” translates into unnecessary costs to the healthcare system as well as unnecessary discomfort and potential side effects experienced by the women. In a resource-limited environment, however, patients are unlikely ever to receive a diagnosis confirming their “true” disease state. In such settings, treatment for *suspicious* precancerous lesions might in some cases be “treatment” for *subclinical* disease likely to exist in women determined to be at high risk for disease. Speculation about some level of preventive effect is based on what is known about the natural history of cervical cancer. Treatment with cryotherapy potentially may reduce the probability of developing cancer or precancerous lesions in women at risk of the disease for at least 5 to 10 years (Lonky et al 1997). If a decision to treat suspicious lesions is made, cryotherapy, cold coagulation or electrocautery are the least expensive and least traumatic procedures. Also, because these methods are noninvasive, unlike LEEP which involves actual removal of tissue, they can be provided at the lowest possible level of the health system by nonphysicians.

### **NOTES**

<sup>1</sup> “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” (PATH 1997)

<sup>2</sup> In general, the World Bank suggests that any intervention whose cost is less than \$100 per DALY gained is worth investing in as a substantially cost effective public health program (World Bank 1993)

<sup>3</sup> The results of this preliminary study—involving 309 sexually active patients using cytology and occasional histology as a gold standard—revealed a sensitivity of 87% and a specificity of 84%. A false negative rate of 12.6% represents a decided improvement over the 15–40% false negative rate that has persisted with cytology alone during the past 10 years. The false positive rate was 16% (Abrams 1990)

<sup>4</sup> “Downstaging” is the systematic attempt to find cancer cases at ever lower levels of severity. Using such an approach, over time, the proportion of patients whose disease is discovered when it is still curable should increase and the proportion of incurable cases should, in turn, decrease.

<sup>5</sup> See “Visual Inspection for Cervical Dysplasia: Preliminary Evaluation Studies in Indonesia (1992–1994),” “Cervical Cancer Screening in Women Attending a Family Planning Clinic in Nairobi, Kenya,” “Zimbabwe Cervical Cancer Screening Study, and “Cape Town Study South Africa” in Gaffikin L et al (eds) 1997 *Alternatives for Cervical Cancer Screening and Treatment in Low Resource Settings*. JHPIEGO Corporation, Baltimore, Maryland. A Report of the Proceedings of the JHPIEGO Board of Trustees Workshop held 21–22 May 1997.

# Recommendations

The following recommendations were derived from the various plenary discussions held during the 2-day workshop

- 1 If morbidity and mortality due to cancer of the cervix are to be measurably reduced, cervical cancer screening and treatment programs must be implemented for *at risk* women on a national or *large scale basis*
- 2 The test qualities of visual inspection have proven to be reasonably consistent across the various investigative studies to date, including those for which only preliminary data are currently available. Once ongoing studies are completed, efforts should shift to investigating how visual inspection performs in the field under more routine health delivery (versus field research) conditions, and how the benefits of such visual inspection based screening programs could outweigh program limitations, including the potential for overtreatment
- 3 In addition to documenting further the efficacy and safety of visual inspection under different field conditions, such applied research projects should answer important questions related to the practicality, feasibility and, most important, the acceptability of visual inspection-based screening programs among the target population

Large-scale visual inspection-based screening programs should have the following characteristics

- As a primary means of screening, the use of visual inspection should enable the *largest proportion* of at-risk women to be screened at least once during their lives, preferably more frequently, if feasible
- In countries where cytology programs are well established and functioning in at least part of the public sector, visual inspection could be used as an adjunct to cytology or as the primary means of screening, if desired, to reduce program related costs. Confirmation of disease as well as treatment should take place at whichever level of the health system supports the least loss-to-followup, balanced by appropriate treatment
- In countries where cytology programs exist only in the private sector, visual inspection could be considered the primary screening method in the public sector—with referral for diagnostic testing, if practical, or treatment on the spot if significant loss to followup is likely
- In countries where, in effect, no screening exists, visual inspection may be the only feasible option for screening for precancerous lesions. Practical ways to increase sensitivity and specificity of this test need to be investigated. This could include, for example, repeat testing over time or treatment protocols that target women most likely to be diseased, given a positive screening test (e.g., women with higher parity and/or women over age 30). In such settings, treatment would need to be on the-spot or close enough in time and proximity to limit loss-to-followup

## Working Group Recommendations

Specific recommendations in the areas of screening, treatment and programming were developed by small working groups during the afternoon of Day 2. Key points from those groups, presented in the final plenary meeting, are summarized below.

### Screening

- The gold standard in any studies to document further the test qualities of visual inspection should be colposcopy at a minimum, biopsy wherever possible
- Standardization of what constitutes visual inspection “test positive” is critical. At a minimum, the threshold of test positive should be acetowhite change. More exact definitions and teaching aids will improve or maintain acceptable test qualities in the field.
- The threshold defining who is “diseased” (e.g., high- or low-grade lesions) and thus who should be treated should reflect the epidemiology of disease in that country. In unscreened populations, diseased women constitute prevalent cases. In such settings, treating all cases of precancerous lesions might result in a greater immediate programmatic impact. On the other hand, in screened populations—where diseased cases are new (incident) ones—treatment should be targeted at high-grade lesions most likely to progress.
- A test with 60% sensitivity or above should be considered a viable screening option for picking up cases of disease in settings where the current screening option has comparable or similar sensitivity, or no screening option exists.
- A screening test should have a specificity of 70% or above to be considered a viable option for correctly identifying those without disease if cryotherapy is used as the treatment modality. Higher specificity is recommended for situations in which LEEP is used to treat precancerous lesions.

### Treatment

- Additional research is needed on the natural history of disease or disease progression in the presence of various cofactors (in particular HIV).
- Further studies (including examination of treatment failure rates among HIV-positive women) need to be conducted to determine the most appropriate treatment modality in countries where HIV prevalence is high.
- The role of cold coagulation and electrocautery as treatment options should be further investigated.
- Appropriate counseling is critical as a means of informing women about their screening results and of assisting them in deciding what further action—including treatment—they should take.
- Based on the results of what is likely to be an imperfect screening test, the woman, together with her provider, should decide whether or not to treat. This decision should be consistent with national policy, which dictates how public healthcare funds are spent.

- The projected cost to the health system of potentially overtreating some women should be balanced against costs currently incurred by the system in treating women with more advanced disease (which requires more expensive treatment modalities)
- The projected “cost” to a woman (and her family) of potentially overtreating her when no disease is present should be balanced against the potential benefit a woman might perceive she has gained from being protected from advanced (clinical) disease for at least 5 to 10 years

### **Programming**

- A priority for cervical cancer programs should include primary prevention aimed at reducing the risk of acquiring human papillomavirus (HPV) and developing precancerous lesions (e.g., reduced parity through family planning, safer sexual practices to reduce sexually transmitted diseases [STDs] through information, education and communication [IEC] and condom promotion)
- Health policy- and decision-makers and providers need to be sensitized about the new data regarding screening and treatment options and encouraged to develop context-specific plans to integrate these options into existing cervical cancer programs
- Health delivery settings—in which offering cervical cancer screening and treatment would be most advantageous to women and the health program as a whole—need to be identified
- Ways of integrating cervical cancer screening and treatment services into existing women’s health services are critical in resource-limited environments

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