



Western Kenya Cervical Cancer Prevention Project (WKCCPP)

*A collaboration with the Ministry of Health,
Mandeleo ya Wanawake Organization, and
Kenya Cancer Society*

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Figure 1. Overview of WKCPP Coverage Area by Division (Busia District, 2000–2004)

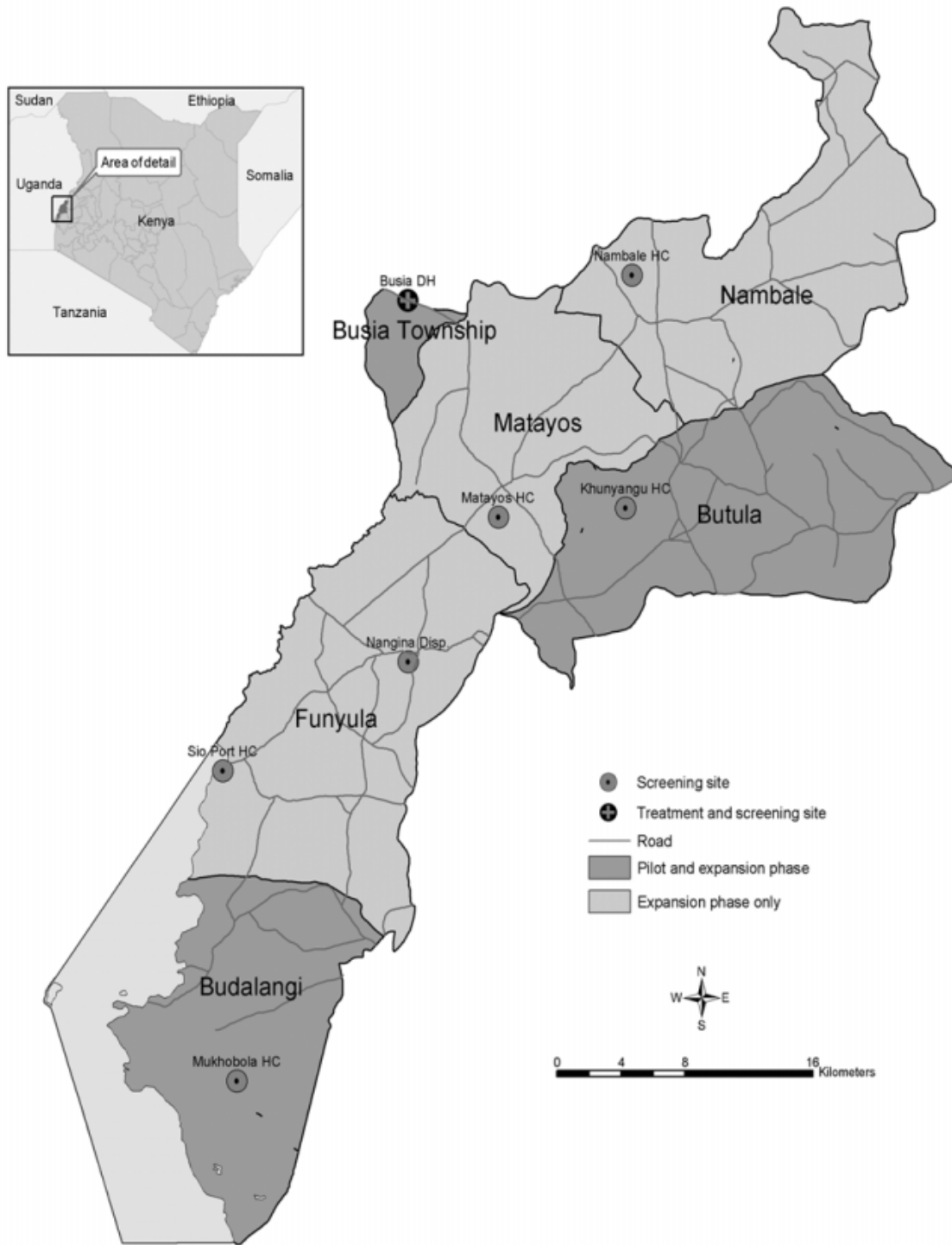


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Executive Summary

The Western Kenya Cervical Cancer Prevention Project (WKCCPP), implemented from 2000 to 2004, was a collaborative project to develop and evaluate a model cervical cancer prevention program suitable for rural, low-resource settings in Africa. The Ministry of Health (MOH), Maendeleo ya Wanawake Organization (MYWO), and the Kenya Cancer Association (KECANS) were partners with PATH in the project. Specific objectives were to test a comprehensive model of clinical care and community mobilization; provide an evidence base that will be useful to the Kenya MOH; to build national and local capacity for clinical care, community outreach, and program management related to cervical cancer prevention; develop useful tools and materials; and encourage and support development and adoption of a national strategy for cervical cancer prevention.

The project was carried out in Busia district in Western Province. Women 30 to 39 years old were the focus of the project, since they were most at risk for treatable, precancerous disease. The project was implemented in three phases: (1) a preparatory phase from February 2000 to October 2000, (2) a pilot phase in three divisions from November 2000 to October 2002, and (3) an expansion phase covering the whole district from November 2002 through March 2004.

The clinical care was based primarily on screening of women at health-center level by nurses using visual inspection with acetic acid (VIA), with visual inspection with Lugol's iodine (VILI) being added to the screening algorithm later in the project. Since it was not considered feasible or cost-effective to offer treatment at every facility offering screening, women were referred to the district hospital for further management after a positive screening test. Nurses at the district hospital carried out cryotherapy, and more complicated cases were referred to the provincial hospital.

Several strategies were employed to mobilize women to seek cervical screening services while creating a supportive community and family environment, and to encourage women to complete needed follow-up care. These included volunteers with incentives and paid supervisors (MYWO) and volunteers without any financial incentives linked to health centers and women's groups.

During the life of the project, nearly 2,400 eligible women were screened, 75 women with eligible precancerous lesions received treatment, and 12 others were referred to provincial level. WKCCPP clearly demonstrated that cervical cancer prevention services based on visual inspection and cryotherapy performed by nurses can be established and sustained in rural Kenya with relatively modest start-up requirements and supports. The clinical research demonstrated that:

- Using VIA to screen women detects a reasonable proportion of women with disease (sensitivity) and is feasible and affordable.
- Combining VIA and VILI for screening is likely to be easier and more accurate.
- Centralizing triage and treatment at the district-hospital level is efficient and probably enhances quality of care, but risks loss to follow-up.
- Adding VILI as a triage test for women with VIA-positive results greatly reduces the number of false positive results.
- Having specially trained nurses do cryotherapy is safe and acceptable.
- Administering cryotherapy without biopsies has minimal risk of missing cancer.

Community mobilization presents many challenges, but the project identified several useful lessons from the research and from feedback provided by participants at many levels:

- *Knowing other women who have been screened* is a powerful determinant in a woman's decision to be screened and may even offset other barriers.
- Building up knowledge and *support among community leaders* is critical for creating an environment that helps women overcome the natural barriers to screening.
- Outreach strategies that work *through church, school, and women's group networks* are most effective.
- Reaching eligible women while they are attending health facilities ("*in-reach*") is also very effective.
- Since travel is a barrier to many women, it is critical that women who do attend for screening *receive timely care and are not turned away*.

Establishing clinical services alone will not achieve the desired disease and mortality reduction unless several critical components are in place, including:

- Effective mechanisms for mobilizing women to take up the service.
- Basic health services with adequate staff and supplies.
- Adequate supervision to ensure quality of care is maintained and staff are complying with program guidelines such as target age group and recordkeeping.
- Specialist services at provincial level to manage complicated cases.
- Key indicator data to enable effective program management.

WKCCPP experience confirmed several features of the model program:

- A coverage target of 75 percent of eligible women screened once over five years does not place too heavy a burden on clinical services at health facilities.
- Both clinical services and community outreach for cervical cancer prevention can be integrated into other ongoing activities.
- Women in their 30s are the most appropriate age group.
- The recurrent cost (without start-up costs) of screening and treatment services is affordable.

Issues that need further attention as scale-up proceeds include strengthening counseling for screen-positive women, integrating cervical cancer indicators into existing health information systems, refining ways to maintain clinical skills, and strengthening referral links.

At national, provincial, and district levels, through WKCCPP and other efforts, there is now a critical mass of clinical capacity, training resources, and program experience that should be sufficient to guide and sustain a cervical cancer prevention service in Kenya. The need is evident, a workable model has been validated in WKCCPP, and women have shown they are willing to participate in the program. With commitment at national and local levels, an affordable and effective cervical cancer prevention service could be phased in over the next five to ten years, and thousands of women's lives could be spared.



Introduction

Cervical cancer is the leading cause of cancer death among women in the developing world.¹ In Kenya it kills more people, male or female, than any other cancer and creates a heavy burden for women in the prime of life, for their families, and for the health care system. Age-standardized rates for Eastern Africa are among the highest in the world and are more than three times the rates in Europe and North America, where intensive screening programs and readily available treatment have brought cervical cancer incidence down from similarly high levels nearly a century ago. Screening programs based on repeated cytology require sufficient numbers of skilled technical personnel to take and read smears, adequate laboratory services with supplies and quality control mechanisms, and good communication and transport systems to get specimens in and results back to women, along with trained health workers and equipment for precancer treatment. Several efforts were made within Kenya in the past decade to tackle this problem, but the goal of a nationwide, affordable, and sustainable program to control cervical cancer has yet to be achieved.

The constraints of limited infrastructure and resources in most developing countries and the low level of awareness of opportunities for preventing the disease stimulated the formation in 1999 of the international Alliance for Cervical Cancer Prevention (ACCP), with funding from the Bill & Melinda Gates Foundation. The purposes of the ACCP are to develop and evaluate innovative approaches in order to reach more women at high risk of cervical cancer with effective and feasible screening and treatment services and to persuade policymakers and program managers to make it a priority.

The Western Kenya Cervical Cancer Prevention Project (WKCCPP), implemented from 2000 to 2004, was a collaborative project that built on local initiatives and the work of PATH, a member of the ACCP. PATH has partnered with the Kenya Cancer Association (KECANSAs), Maendeleo ya Wanawake Organization (MYWO), and the Kenya Ministry of Health (MOH) to carry out this initiative.

The goal of the project was to develop and evaluate a model cervical cancer prevention program suitable for rural, low-resource settings in Africa. Specific objectives were to:

- Test a comprehensive model of clinical care and community involvement, answering key questions about aspects of clinical care, community involvement, and program design.
- Provide an evidence base that will be useful to the Kenya MOH (and other similar countries) in deciding how to design a sustainable national program.
- Build national and local capacity for clinical care, community outreach, and program management related to cervical cancer prevention.
- Develop tools and materials, such as training curricula and visual aids.
- Encourage and support development and adoption of a national strategy for cervical cancer prevention.

The specific research questions were nested within the model program. Critical clinical questions to be addressed concern the performance of new screening tests based on visual inspection; the

performance of visual tests as compared to cytology for triage of screen-positive women; and the safety, acceptability, and effectiveness of cryotherapy as done by non-physicians. Important community involvement questions included the effectiveness of different outreach strategies in terms of women coming in for screening or completing follow-up for recommended care, and sociocultural, demographic, and service delivery factors affecting women's participation in screening. To evaluate overall program design, the project tracked screening coverage, training needs, quality of care, start-up and recurrent costs, and cost recovery success and challenges.



Project Implementation

Project Organization

The WKCCPP was based on collaboration among partners who brought complementary skills and resources to the project. The MOH provided the essential clinical infrastructure of health facilities, care providers, and district management. Local health management teams allocated necessary funds for supplies. MYWO focused its efforts on developing links with the community through a network of MYWO community health workers (CHWs) who did both group and individual outreach. KECANSA assisted primarily by providing oncology expertise for training and materials development. PATH provided local coordination, technical assistance and training, materials development, research design, data management and analysis, and funding. Experts in reproductive health and representatives of relevant governmental and nongovernmental agencies constituted a Technical Advisory Group that met periodically to provide guidance to the project.

Location and Participants

The project was carried out in Busia district in Western Province (see Figure 1). The district is bordered on the west by Uganda and Lake Victoria and is a fertile highland area perched 1,000 meters above sea level. The region is generally underdeveloped economically and is underserved by education and primary health services, reflected in the fact that the infant mortality rate in Busia is almost 50 percent higher than the national average.² HIV sero-positive rates, although lower than the national average, are estimated at 12 percent among women aged 25 to 39 in Western Province.³ Busia had a population of about 370,608, including an estimated 19,995 women in the age range of 30 to 39 years at the start of the project.⁴ Although district-specific cancer rates are not available in Kenya, Busia was selected for the project because national referral hospital records suggested a high proportion of cervical cancer patients coming from Western Province and Busia had both a functioning district hospital and a supportive District Health Management Team (DHMT). Although there was no pathologist in Western Province, there was a provincial gynecologist posted at the Provincial General Hospital in Kakamega at the start of the project who could provide specialist support for referred patients.

Women 30 to 39 years old were the focus of the project. Given the limited resources available, the project gave priority to those most at risk of treatable, precancerous disease. Although data on cervical cancer incidence for Kenya are limited, most studies to date agree that the peak age for invasive cervical cancer is in the 40s.^{5,6} Even in studies based on urban hospital admissions

(which usually under-represent older women), less than 20 percent of cases identified were among women under 35 years old.^{7,8} Since the natural history of cervical cancer suggests that precancerous disease starts about ten years earlier than invasive cancer and that lesions among women in their 20s tend to be transient and self-resolving, the project was directed at women in their 30s. Women outside the project age range were screened if they requested it, but they were not included in the study data. Women who were visibly pregnant (that is, at least 3 to 4 months gestation) were encouraged to return for screening six weeks after their pregnancy was completed, since cervical changes later in pregnancy might complicate the VIA reading and the pregnancy might make the exam less comfortable for women.

Nurses at dispensary, health center, and district-hospital level were the primary providers of care and recorded all patient information. Clinical officers and district health management provided supervision and training support. Gynecologists at provincial and national level managed patients who were referred. CHWs, social development assistants, and various community leaders were involved in outreach to women in the community.

Project Timing

The project was implemented in three phases. The *preparatory phase* from February 2000 to October 2000 consisted of administrative approvals, completion of the research design, a facility assessment, formative research on community attitudes and knowledge, procurement of equipment and supplies, preparation of recordkeeping forms, training of CHWs, initial clinical training of health center nursing staff in the three pilot divisions and at the district hospital, and ethical review.

The *pilot phase* from November 2000 to October 2002 was conducted in the district hospital in Busia Township and three divisions (Funyula, Matayos, and Nambale) of the five in the district. The main objectives of the pilot phase were to validate the two-stage algorithm for screening and treatment of cervical dysplasia, to refine the community mobilization component, and to gather cost information. Key questions included the effectiveness of volunteer outreach workers, VIA for screening, and cryotherapy performed by nurses. In order to generate enough screen-positive women being referred to the district hospital for triage testing and treatment, the recruitment goal for this phase was about 1,400 women. Workshops were held at national, provincial, and district level in March 2002 to report preliminary results from the first 1,170 eligible women screened. By the end of the pilot phase about 1,600 women had been screened.

The *expansion phase* of the project was from November 2002 through March 2004. The purpose of this phase was to evaluate the performance of the model under routine-use conditions, with limited external inputs, and to complete the transition to full local management of the services. After an initial facility assessment (see Appendix 1) to determine readiness for adding cervical cancer screening services and training of additional staff, the project expanded to the remaining two divisions of the district. Recordkeeping was streamlined, new outreach strategies were added, and training and supervision were gradually transferred to district staff. In this phase, project staff also provided assistance to the MOH in the development of a national strategy and guidelines

for cervical cancer prevention that, given the resource limitations of the setting, provide the best chance for identifying and properly treating women at risk of developing cancer.

Clinical Care Model

Screening

The first step of the screening process was a group or individual counseling session to explain the purpose and process of screening. A flipchart was used to assist in this process (see Appendix 2). During an individual counseling session, informed consent was obtained and pregnancy status was assessed. Syndromic assessment for sexually transmitted infections was part of the examination. For most of the project, women were screened primarily at health-center level by nurses using visual inspection with acetic acid (vinegar), known as VIA. VIA involves swabbing the cervix with 3 to 5 percent acetic acid, waiting at least one minute, and then examining the cervix with a strong light (lamp or torch).⁹ Distinct well-defined acetowhite lesions in close proximity to the squamocolumnar junction are considered to be precancerous cervical intraepithelial neoplasia (CIN) and constitute a VIA-positive test. Women with results suggestive of cancer are also considered positive and are referred for further evaluation.

Late in the expansion phase (December 2003), the screening test was adjusted to add VILI as part of the algorithm. This was done after experience at the district hospital level and the completion of international studies involving more than 55,000 women in Asia and Africa showed VILI to be easier to interpret and significantly more sensitive than VIA.¹⁰ Lugol's iodine stains normal cervix tissue brown, while precancerous lesions (CIN) and cancerous lesions appear as a mustard yellow color. During the last few months of the expansion phase, then, the procedure followed was to apply acetic acid first to identify key cervical landmarks and any acetowhite areas and then apply iodine to make the final assessment as to whether a real lesion was visible.

Women with a positive VIA test in the pilot or early expansion phase, or a positive VILI test in the late expansion phase, were considered screen-positive and were counseled to go to the district hospital for further evaluation (“triage”) to determine what management was needed. Test results including a diagram of the lesion location on the cervix were noted on specially designed, client-retained cards (see Appendix 3) to be shown at the district hospital.

Triage

Since it was not considered feasible or cost-effective to offer treatment at every facility offering screening, women were referred to the district hospital for further management after a positive screening test. Although many experts consider it to be safe and appropriate to provide treatment simply on the basis of VIA or VILI,^{11,12,13} even though the tests identify some women as being at risk when they do not actually have a lesion that needs treatment, the WKCCPP project was designed to test the value of triage using tests likely to be feasible for district hospitals. Initially this focused on visual inspection with acetic acid and 4x magnification (VIAM) using a hand-held, battery-powered

binocular device called the AviScope™. In November 2002 staff at the district hospital added VILI to the triage routine. For comparison research purposes, Pap smears were also taken as part of the district hospital visit, and the attending nurses did colposcopy after completion of competency-based training. The order of procedures during the triage session was: individual counseling, signing of informed consent, assessment of pregnancy status, speculum exam, taking of the Pap smear, VIA, colposcopy, VILI, and directed biopsy when indicated by colposcopy.

The use of a reference standard consisting of colposcopy and directed biopsy served two purposes. The treatment decision was supposed to be based on colposcopic impression (with lab results coming later to identify any cancers that might have been missed) to reduce the number of visits and the loss to follow-up care. However, district hospital staff usually preferred to wait for the biopsy result to come back before offering treatment. Second, the use of colposcopy allowed comparison to conventional cytology and the evaluation of the proposed triage methods: VIA, VILI, and VIAM. Women for whom pregnancy was known or suspected (based on a set of questions and/or a pregnancy test) were examined for triage assessment if they wished, but biopsy and cryotherapy were delayed until at least six weeks after pregnancy completion to avoid any risk of disturbing the pregnancy or of causing the procedure to be blamed if a natural miscarriage occurred soon after.

Treatment

Cryotherapy treatment was done if the lesion met the eligibility criteria:

- No suggestion of invasive cancer.
- Lesion small enough to be covered by the probe surface.
- Edge of lesion closest to canal is visible with no more than 2mm extension into the endocervix.
- No extension of the cervical lesion onto the vaginal wall.

A double-freeze technique was used with two 3–minute periods of freezing separated by a 5–minute period to allow thawing of the frozen cervical tissue. Nitrous oxide (N₂O) gas was used to achieve the freeze. Consistent with current MOH policy related to invasive gynecologic procedures such as intrauterine contraceptive device insertion, prophylactic antibiotics were provided at the time of the treatment. Those who complained of cramping, lower abdominal pain during or immediately after cryotherapy were given a prescription for several doses of an analgesic such as ibuprofen. After the procedure and when women had been allowed to dress in private, women were counseled about self-care after cryotherapy, including abstinence from sexual intercourse for four weeks, and were given explanations of signs of complications. Women were given a pictorial after-care flyer (see Appendix 4) and were reminded to return for follow-up visits.

Clients who received cryotherapy returned for a supportive visit between 1 and 3 months after the treatment and followed up again at one year to assess cure and offer further management to those with persistent disease. The 1- to 3-month visit was added based on local providers' strong beliefs about women's preference to be seen relatively soon after treatment. This visit was designed to reassure women that providers cared about their

recovery and to provide an opportunity to reinforce the reminder to return for the one-year follow-up visit.

Referral for specialist care

Patients with precancerous lesions not suitable for cryotherapy, with lesions suggestive of invasive cancer, or with frank cancers were referred to the provincial hospitals in Kakamega or neighboring Kisumu. At provincial level, gynecologists carried out final diagnosis, staging if cancer was present, and surgical treatment as appropriate. Women needing radiotherapy were referred to Kenyatta National Hospital in Nairobi.

Palliative care

Although the project did not expect to identify many women with advanced cancer among women 30 to 39 years of age, it was clear that older women with cancer were being identified and that some women with early disease likely would not be able to access treatment services. Clients with cancer or who were unable to travel to Kisumu, Kakamega, or Nairobi for cancer care were referred to palliative care services at the provincial level, usually the Kisumu Hospice. In addition, there was an effort to enhance community-based palliative care services using the CHWs working with MYWO and clinic/hospital-based services using the health providers. A problem-based clinical record and management planning tool was developed to allow providers to identify the palliative care needs of women with cervical cancer. This record also served as a continuing care record and was suggested as a useful patient summary when transferring care to a referral center or other services. MYWO and KECANSA collaborated with PATH staff to develop a palliative care field manual that was printed and disseminated locally and nationally (see Appendix 5).

Evaluation of clinical activities

While the basic model of care included screening, triage by VIAM and/or VILI, and cryotherapy treatment, several additional steps were included to aid in evaluating the safety, acceptability, and effectiveness of screening and treatment.

- Pap smears were taken at the triage visit and again at the one-year follow-up visit.
- Colposcopy was carried out at the time of triage and again one year after treatment (to assess cure), and directed biopsies were taken from women who had identifiable lesions at colposcopy. In order to avoid observer bias, two providers examined each client independently, with one performing VIAM and the other performing colposcopy. Clients were considered to be true negatives if they were negative on either colposcopy or biopsy. Only clients with positive biopsy results were considered true positive cases of CIN or cancer.
- During the expansion phase, the performance of both VILI and VIAM were compared to Pap smear using the same reference standard of colposcopy and directed biopsy. Again, two providers usually performed the examinations, with one providing VIA and VILI and the other performing VIAM and colposcopy.
- In the pilot phase, in order to assess the safety of cryotherapy in this population, women who were treated with cryotherapy were asked to make additional facility visits at 1 week, 1 month, and 3 months after treatment to be interviewed about complications and, if necessary, examined.

- A special follow-up survey was carried out to contact the first 25 women who were treated with cryotherapy to get more in-depth information about their posttreatment experience.
- A pair of international experts reviewed Pap and histology specimens from the pilot phase; where their results conflicted with the local reading, a final consensus finding was determined by the international experts and used for patient care as appropriate and for all data analyses.
- To evaluate the accuracy of VIA screening, a substudy was organized during which a gynecologist spent a month in Busia in 2002 attending screening sessions at pilot health centers and performing colposcopy on all women who came in for screening on those days. The colposcopy assessment, done without knowledge of the attending nurse's VIA screening result, provides an unbiased standard for both positive and negative screening results and makes it possible to estimate the accuracy of VIA in a way that is not possible from the larger study, where women with negative results received no further evaluation (verification bias).

Community Mobilization

The main roles of outreach workers were to mobilize women to seek cervical screening services while creating a supportive community and family environment, and to encourage women to complete needed follow-up care. Outreach workers also played several secondary roles, which included developing and field-testing materials such as an outreach job aid, a client brochure, and clinical counseling aids; mobilizing women for clinical training sessions; and participating in collecting data for evaluation and for special research sub-studies associated with the project.

Mobilizing women and building a supportive environment

During the *preparatory phase* community-based formative research was undertaken as a first step in developing a locally relevant community outreach and follow-up strategy. The research also provided information for developing materials for later outreach worker training, clinical provider counseling training, and client counseling aids. A total of 27 focus groups and 18 key informant interviews were carried out among opinion leaders (religious leaders, educators, government administrative leaders, CHWs/traditional birth attendants, women's group leaders [WGLs]) as well as women aged 30 years and above and their spouses. A total of 69 men and 185 women participated in the research.

Several important considerations emerged from the formative research and shaped the strategy:

- Community mobilization efforts that made optimal use of existing local capacity are more likely to be sustainable; therefore, the strategy was scaled to the limited resources and local capacity available, in order to enhance the likelihood of sustainability.
- The approach was peer-based and interactive.
- Recognized community opinion leaders (including chiefs, assistant chiefs, clergy, school teachers, WGLs, CHWs, and health personnel) were involved in outreach efforts to enhance both mobilization activities and overall community-wide acceptance.
- Key messages were framed within a broader discussion of good health practices that built on a limited knowledge base about women's reproductive organs.

- Training materials for CHWs included other health topics of concern to women, such as sexually transmitted infections and HIV/AIDS.
- Active support by male partners of women was encouraged.
- Working through women’s groups was a primary strategy.
- Income-generating activities were included in order to ensure that CHWs could support their outreach activities.

The strategy in the *pilot phase* was based on a model developed by MYWO, a national grassroots women’s organization. It relied on volunteer CHWs (who received a monthly transport allowance) and paid supervisory staff. During this phase, the MOH did not organize or carry out any significant community mobilization activities. MYWO has an estimated individual membership of two million and over 25,000 women groups, with a strong presence in rural and otherwise very marginal communities throughout Kenya. MYWO had practical experience in taking health-related services to the community and also participating in community-based research, program monitoring and evaluation, and IEC materials development.

MYWO project staff in Busia consisted of three division coordinators and one district supervisor. These supervisors recruited, trained, and coordinated the activities of three teams of CHWs to work in the pilot divisions of Nambale (10 CHWs), Matayos (10 CHWs), and Funyula (15 CHWs). CHWs needed to be literate, have previous experience in outreach, be familiar with women’s health issues, and be prominent leaders in their communities. Each CHW covered between two and seven villages. During this phase, CHWs received a monthly stipend of KSh600 (about US\$8) to compensate for transport costs and time spent, with the understanding that this support was temporary until income-generating activities could replace these funds (by the end of the pilot phase). Other items provided to CHWs to enhance their productivity were bicycles, watches, badges, and bags for their documents.

MYWO CHWs and supervisory staff went through a one-week training program (see curriculum in Appendix 6). The training reviewed basic female reproductive tract anatomy, natural history of cervical cancer and its prevention (review of VIA screening, diagnostic tests, and cryotherapy), effective client counselling and outreach, mapping communities, collecting data, and filling out forms. Annual refresher trainings were scheduled for CHWs to address anticipated turnover. CHWs and staff completed an additional one-week training on income-generating strategies during the pilot phase. The training focused on the “CHW Empowerment Process,” a curriculum designed to develop the skills needed for creating individual and group income generation.

CHWs and supervisors carried out regular community mobilization, outreach, and follow-up activities to inform and motivate women in their community about the need to seek screening at their local health center; to refer eligible clients; and to follow up women who were registered but not yet been screened, who had been referred to the district hospital but had not yet gone, and those who had undergone treatment. Outreach activities varied and included:

- Attending and organizing meetings with local male and female leaders, clergy, school teachers, and other opinion leaders to talk about the new screening services.
- Organizing and/or participating in awareness-raising events at public “barazas,” funerals, chiefs’ camps, women’s groups, parent-teacher associations and church groups.

- Visiting clinic staff to identify clients in their areas needing follow-up care.
- Carrying out individual visits during which CHWs encouraged male partner support, gave practical information on facility hours and fees, and urged women to complete follow-up care.

The aim at each venue was to identify eligible women to be screened, list them in a register, issue a client card (see Appendix 3), and encourage them to commit to getting screened. At smaller events such as women’s group or church group meetings, or during home visits, CHWs addressed concerns about the examination and cervical cancer. A client brochure was used to convey essential messages (see Appendix 7) and a poster was developed and displayed (see Appendix 8 for original and modified versions).

During the *expansion phase*, new outreach strategies were added to use of the existing MYWO CHWs. In the new expansion divisions, where MYWO was not established, existing governmental outreach capacity was identified during a facilities needs assessment and was activated, including government volunteer CHWs attached to health centers and social development staff (Ministry of Culture, Sports, Education, and Welfare). These changes were made partly in response to an economic analysis that showed that a more cost-effective mobilization strategy was needed. Each of these new strategies relied on pre-existing resources and received no additional project funds. The new outreach workers in the expansion sites went through an intensive 1-day orientation to the screening programs, with one refresher training 3 to 4 months later. Training materials were provided, including a job aid that outlines essential information needed for conducting outreach activities (see Appendix 9).

The Nangina dispensary coordinated the efforts of ten family planning CHWs who were supported through the Family Planning Association of Kenya (FPAK) and supervised by dispensary staff. At the Khunyangu health center, facility staff had organized and supported ten CHWs; CHWs received free services and preferential treatment for themselves and their families as incentives for their efforts. At the Mukhobola health center, ten CHWs conducted a range of health outreach activities and were supervised by clinic staff; most were financially supported (received bicycles and a monthly stipend) and supervised by World Vision, an international NGO.

The District Social Affairs office worked through their existing community networks to organize and supervise two groups of 25 to 30 WGLs to promote cervical cancer prevention activities. The goal was to train one or two WGLs per sublocation to ensure optimal geographic distribution. Recruitment and follow-up of eligible clients and those needing further care were to be coordinated through individual clinics and the staff at the district hospital, who were to notify clinic staff about any women needing follow-up care.

During the expansion phase, MYWO continued to work in existing divisions and focus their efforts on building income-generating initiatives among their CHWs to replace the monthly stipend that had been discontinued. MYWO supervisors continued to receive salaries and transport allowances in recognition of their extra roles in research and evaluation. To increase coverage capacity and lessen the outreach load among volunteer CHWs, 30 additional WGLs, geographically distributed in the three MYWO divisions, were also trained and supervised by MYWO. Newly recruited MYWO WGLs went through a 3-day training program—similar in content to training carried out among CHWs during the pilot phase but shorter, to meet cost constraints.

Home-based palliative care

MYWO coordinators (who were also nurses) received training in the delivery of home-based palliative care for those with advanced cancer; they coordinated with district hospital staff to identify and manage cases in divisions where MWYO had outreach activities. In the remaining divisions, health center and district hospital staff were responsible for any palliative follow-up that was needed.

Evaluation of community activities

Both quantitative and qualitative data were collected and a special research substudy was undertaken to aid in evaluating the overall effectiveness of the community mobilization strategies employed in this project.

- During the pilot phase, a data collection system was devised in order to monitor the extent, intensity, and relative costs of monthly community mobilization activities. CHWs completed field activity logs each month. These forms were compiled by supervisors and extracted for entry into the project database. Data were kept on the number of women enrolled each month per CHW, the total number of mobilization activities (differentiated by event type), number of referrals made at each event, and the total number of hours CHWs spent carrying out activities each month. Screened women could be traced back to individual CHWs through their client numbers.
- During the expansion phase, data collection involving outreach workers was greatly scaled back due to the practical difficulties of asking volunteers to complete detailed records. Volunteer outreach workers in all divisions were asked only to submit a monthly summary of referrals, the number of events they either attended or carried out (by event type), and what sublocations these activities were carried out in. Data were aggregated at the sublocation level.
- Monthly progress monitoring reports were submitted by MYWO and PATH field staff and were treated as project monitoring data. These reports included information on difficulties and challenges that were being faced by outreach workers as well as successes.
- At the end of the project, a community survey was carried out among screened and unscreened women in order to determine key factors that influenced women's screening decisions.
- Field reports from site visits by project staff also provided monitoring data.

Program Issues

To achieve success in introducing and sustaining a new health intervention like cervical cancer prevention, consideration must be given as to how it is integrated into existing services, how to optimize access and utilization, how health personnel will acquire and maintain the needed skills to carry it out, how to ensure high quality of care, and how costs will be covered. Program managers need clearly defined indicators of success and adequate data for monitoring progress on those indicators. Along with the selection and evaluation of specific medical procedures and of community outreach strategies, these broader functions of program management were a critical part of WKCCPP.

Integration with existing services

New cervical screening and treatment services at primary and secondary level were added to existing reproductive health services. For the sake of sustainability and in consideration of the MOH policy favoring integrated rather than vertical services, the project was built on existing staff, facilities, and systems. The only additional equipment or supplies needed for screening were vinegar and a torch and batteries. Most facilities already had examination tables, specula, privacy screens, and basins. Initially, there were some attempts to set aside particular times for cervical screening, but most facilities eventually decided just to include those clients in their regular schedule of integrated services. Supervision and record systems (see below) were also integrated into existing structures.

The benefits of integration went both ways. Investments in strengthening the existing base of skills, such as speculum exam and knowledge of reproductive tract anatomy, had payoffs for family planning and Safe Motherhood Program care also. Women who came for cervical screening received treatment for any STIs or other health problems identified during the exam. Client recruitment was also assisted by the integrated approach, since about 30 percent of family planning clients were 30 years or older. The key issues in promoting screening recruitment among family planning clients were: focusing on women in the correct age group and not repeating screening among those already screened.

Coverage as a measure of access and utilization

Access refers to service availability, while utilization refers to women's decisions to attend for screening and any follow-up care. Actual coverage achieved is the key indicator for access and utilization. Each facility was empowered to set its own schedule for making screening and treatment services available. There was some discussion of providing occasional outreach screening services to dispensaries, but the lack of official transport made that difficult to implement. Health center committees of participating facilities signed memoranda of understanding promising to maintain adequate trained staff and essential supplies on hand to meet service needs. Utilization depended on a combination of service, demographic, and sociocultural factors.

Training

Health center providers were trained to perform screening procedures, while district hospital staff learned screening, triage, and (for research purposes) diagnostic methods. Training was aimed at achieving competency in a particular procedure using a combination of didactic and practical teaching methods. Cognitive learning was assessed using written pre- and post-tests during each course, and clinical skills were assessed during performance of procedures, using a step-by-step learning guide checklist that could be completed by an instructor or fellow student.

Course length was 5 days for VIA, with about 2 days for didactic work and 3 for practical teaching in the clinical setting. Didactic sessions covered basic anatomy, physiology, epidemiology and natural history of cervical cancer, vaginal speculum examination, rationale for VIA, VIA procedure, counseling, referral, principles of treatment, common STIs, and infection prevention. The addition of VILI training added half a day to the course overall. Nurses at the district hospital who performed colposcopy and triage were trained using similar methods, but much more emphasis was placed on the research-related skills of diagnosis (using the

colposcope, taking Pap smears, obtaining directed cervical biopsies, understanding pathology results) and on performing cryotherapy or arranging referral, as appropriate.

Periodic on-site refresher sessions given about every six months during the project were a half day or less in duration. If women were present for screening, then it was possible to do clinical teaching. Otherwise, cervical photos (after application of acetic acid) were shown and discussed. At the district hospital, refresher sessions also occurred, but these lasted usually for one or two days and included didactic teaching as well as practical sessions with many patients.

Initially, clinical teaching was led by a master trainer from PATH Seattle, but by the time of the expansion phase, a gynecologist from Nairobi was qualified as a master trainer in visual inspection, colposcopy, and cryotherapy, and a general physician from Nairobi and a nurse from the district hospital had been trained as master trainers for visual inspection. Course materials consisted of computer slide sets that covered every aspect of the knowledge to be transferred. During the expansion phase, a detailed teaching curriculum on VIA was available to teachers, and parts of this manual were reproduced and given to learners as reference material. In its final published form, the curriculum covers both VIA and VILI (see Appendix 10). A colposcopy and treatment textbook¹⁴ was given to those learning these particular procedures.

Facilitative supervision for high quality care

Project staff initially carried out supervision, but by the expansion phase, it was done in tandem with usual district supervisory visits. The project developed several tools to aid district supervisors. A checklist was developed in collaboration with the MOH to guide the review of basic procedures, availability of key supplies, and accuracy and completeness of client records (see Appendix 11). Sets of cervical photos (after application of acetic acid or iodine) representing different conditions (normal, with lesions, with cancer) were assembled (along with answer keys) for supervisors to use in assessing staff capabilities during routine facility visits. These photo quizzes (see Appendix 12) enabled supervisors to identify problem areas and provide refresher instruction. Tracking the photo quiz scores over time allowed the project to monitor the level of staff skills in the area of screening. A project gynecologist also visited the district hospital at least once a quarter to assess the triage and treatment skills of district hospital staff and provide feedback and refresher training as needed.

Cost of care and self-financing

The project was designed in compliance with Kenya's policy of cost recovery, by which all women paid a registration fee for the screening service except for those receiving an official waiver from their local facility. In the pilot phase, the project supported the cost of treatment for those who participated in the screening program, but in the expansion phase, the district hospital agreed that women needing treatment should pay for their care, as they do for other services. The project conducted an analysis of the incremental cost of adding screening and treatment care to existing services. In addition to providing estimates of the average cost per woman screened and treated, this information was also used to set the actual level of the fees to cover recurrent costs.

Routine program data for monitoring and research

For monitoring and evaluation purposes, data systems were established to collect clinical, community, and general program data. Clinical information was used both for client care and tracking and for evaluating the safety and effectiveness of clinical activities.

Clinical data were drawn from:

- Client-retained cards with identification numbers, screening results, referral for triage if needed, and any treatment and other follow-up notes.
- Individual client screening records (pilot phase) and client screening register (expansion phase, see Appendix 13).
- Individual client treatment and follow-up visit records (pilot phase) and treatment and follow-up visit registers (expansion phase).
- Laboratory slips for Pap and biopsy results.

Community data were drawn from:

- Logs of client characteristics and contacts maintained by MYWO CHWs (pilot phase).
- Monthly summaries of outreach activities (pilot and expansion phase).

Program data were organized primarily for monitoring and included:

- Supervisory checklists.
- Monthly facility reports of number of clients screened, number screen-positive, number visiting district hospital, number who were triage-positive at the district hospital, number treated, and number completing follow-up visits (Appendix 14).
- Pre- and post-tests related to training sessions.
- Photo quiz results.

The project worked closely with the district health management team, including the Medical Records Officer, to ensure that program data systems were compatible with and integrated into existing health information systems.



Project Results

The project answered most of the specific research questions identified as crucial for enabling government decision makers to understand what procedures, systems, and resources are needed to make cervical cancer prevention a reality for Kenyan women. The clinical care model initially proposed was, with minor modifications, shown to be viable and much was learned about how best to organize community outreach efforts. Valuable tools and systems were developed and tested, and a cost analysis was completed. Severe socioeconomic constraints in the district and the general strain affecting the government health care system in Kenya limited the planned scope of the project somewhat, but did not compromise the overall objectives.

Clinical Care Outcomes

WKCCPP results provided important information on clinical practices related to screening and treatment of cervical precancer. Although the project was designed primarily to operate through the existing government system without the special external supports or controls that often accompany research studies, it provided an opportunity to answer several specific research questions that were nested within the demonstration project:

- How does VIA perform as a screening test in this environment?
- How do VIAM, Pap, and VILI perform as triage tests among screen-positive women?
- Is cryotherapy safe, acceptable, and effective when done by trained nurses and clinical officers?

Screening test performance

Of the total 2,385 women who came to a health facility for a screening examination, 1,806 (76%) had a negative result, 489 (21%) a positive result, and 90 (4%) either did not receive a screening exam or had an unknown result. Only 6 percent had a screening result based on VIA followed by VILI (the procedure adopted in the final months of the project), while the rest were screened only by VIA.

More women were screened during the pilot than the expansion phase (Table 1). The increased screening rate during the pilot phase is probably attributable mostly to the intensity of MYWO recruitment efforts during this time. The district hospital screened fewer women overall because, although women in Busia township attended the district hospital for primary screening, it was meant to be a referral-level facility and no special recruitment efforts were made in the township.

Table 1. Women screened in each facility by phase.*

Facility	Pilot No. Screened	% Positive	Expansion No. Screened	% Positive	Total No. Screened
DH	58	35%	41	37%	99
Matayos	540	31%	96	18%	636
Nambale	545	24%	80	17%	625
Sio Port	436	15%	63	5%	499
Khunyangi	N/A	N/A	114	13%	114
Mukhobola	N/A	N/A	139	12%	139
Nangina	22	26%	175	11%	197
TOTAL	1601	24%	708	14%	2309

* Note: Not all client facilities or screen dates are known. Some clients who had screening visits are excluded here because either the screening facility or the screening date is unknown.

Women who were screen-positive were similar to those who were screen-negative in the type of influence encouraging them to come into the health facility, age distribution, and pregnancy status, but differed with regard to treatment for an STI and the visibility of their squamocolumnar junction. The probability of screen-positive women being treated for an STI (n=23, 6%) was 67 percent less (OR=0.33; 95% CI: 0.20-0.53) than for screen-negative women (n=189, 17%), while the probability of screen-positive women having their cervix completely or partially visualized (n=314, 92%) was 2.7 times higher (95% CI: 1.8-4.2) than for screen-negative women (n=867, 80%).

Of the 133 clients who participated in the VIA substudy in 2002, 96 (72%) had negative screening results by a nurse and 37 (28%) were test-positive. All were examined at the same visit by a gynecologist with a colposcope, with 74 (56%) negative and 59 (44%) positive for CIN 1 or higher. Final diagnosis, against which test performance was compared, was based on biopsy result for a positive, and negative biopsy or colposcopy for a negative; clients with positive colposcopy but missing biopsy (24%) were excluded from the analysis. On final diagnosis, 89 (67%) were negative according to either colposcopy or biopsy, 4 (3%) had a low-grade lesion according to biopsy, 8 (6%) had a high-grade lesion according to biopsy, and no clients in this substudy had cancer according to biopsy.

The sensitivity and specificity of VIA from the substudy (Table 2) were within the range of values reported in other studies.¹⁰ A higher sensitivity means that clients are less likely to have a false negative exam in which their lesion is missed. A higher specificity means that clients are less likely to have a false positive exam in which a lesion is identified that doesn't really exist. The higher test-positive rate in the substudy may have been due to nurses being more cautious about missing someone when they knew a doctor would also be examining the client, since the positive predictive values (PPV) from the substudy are a little lower than those of the full study (suggesting more false positives in the substudy).

Table 2. VIA performance.

	Sample Size (n)	Test Positive	Sensitivity (95% CI) ^a	Specificity (95% CI) ^a	PPV (95% CI) ^a
Low-Grade and Higher (CIN 1, 2, 3)					
Substudy	133	28%	54% (25-81) ^b	78% (67-86) ^b	26% (11-46) ^b
Full Study	2385	21%	N/A	N/A	30% (25-36) ^c
High-Grade (CIN 2,3)					
Substudy	133	28%	38% (9-76) ^b	74% (64-83) ^b	11% (2-29) ^b
Full Study	2385	21%	N/A	N/A	7% (5-11) ^c

^a Confidence interval.

^b Based on 102 women who had complete diagnosis.

^c Based on 347 women (out of 489 positives) who had complete diagnosis.

Of the 142 women screened using VILI (6% of overall clients screened), only 19 women were positive (13%), lower than that of VIA (21%). Of these, only four women received a final diagnosis at the district hospital, so we are unable to estimate the PPV of VILI for screening.

The VIA positivity rate varied widely among the different providers, but overall it declined over time from 24 percent to 14 percent, as shown in Table 1 above. This may have been due to improvements in training as the curriculum and teaching techniques were refined by the end of the pilot phase. The ideal VIA positivity rate is expected to lie between 10 percent and 20 percent and generally decreases as providers gain experience. Since VIA and VILI are visual tests whose accuracy improves with provider experience, a sufficient client load during and after initial training is needed in order to develop and then optimize skills.

Triage Test Performance

A total of 472 clients eventually went to the district hospital for triage after screening. More than 80 percent of these had either positive (341) or unknown (45) screening results, but 86 screen-negative women (5% of those with negative screening results) also decided to go to the district hospital for further assessment. Of that total, 385 women (77%) had a final diagnosis based on recorded colposcopy and biopsy results (when appropriate), and the triage performance of VIAM or VILI was assessed on the 369 clients with complete data. Of the women with a final diagnosis, 260 (61%) were negative on either colposcopy or biopsy, 79 (19%) had a low-grade lesion (CIN 1), 36 (9%) had a high-grade lesion (CIN 2 or 3), and 10 (2%) had a cancerous lesion identified by biopsy.

Which test is best? VILI, as done by providers with more intensive training than those who just do screening, clearly had the best performance as a triage test, compared to VIAM and Pap smear (Table 3). By identifying just 33 percent of women as triage-positive, it detected 88 percent of the true positive cases of low and high-grade disease and 100 percent of the high-grade lesions. Because of its high sensitivity and specificity, it had a significantly higher PPV—more than double that of Pap smear. VIAM had a sensitivity nearly as high as VILI, but a much lower specificity. Although the sensitivity of Pap for high-grade lesions is in the same range as VILI, the specificity of Pap was significantly lower than VILI. Therefore, VILI is the most suitable triage test in this setting.

Table 3. Triage test performance.

	Sample Size (n)	Test Positive	Sensitivity (95% CI)*	Specificity (95% CI)*	PPV (95% CI)*
Low-Grade and Higher (CIN 1, 2, 3)					
VIAM	368	61%	89% (81-95) ^a	41% (33-49) ^a	45% (37-52) ^a
VILI	127	33%	88% (68-97) ^b	93% (83-98) ^b	81% (61-93) ^b
Pap smear (ASCUS+)	377	51%	60% (50-70) ^c	51% (44-57) ^c	38% (31-46) ^c
High-Grade (CIN 2,3)					
VIAM	368	X	90% (73-98) ^a	33% (27-40) ^a	15% (10-21) ^a
VILI	127	X	100% (48-100) ^b	76% (65-84) ^b	19% (7-39) ^b
Pap smear (ASCUS+)	377	X	79% (62-91) ^c	50% (44-56) ^c	16% (11-22) ^c

* Confidence interval.

^a Based on 260 clients with complete diagnosis and independent readers for VIAM and colposcopy. Readings that were independent had a lower agreement rate (kappa=0.53) than those done by a single reader (kappa=0.73).

^b Based on 91 clients with complete diagnosis. Readings for VILI and colposcopy that were independent had a similar agreement rate (kappa=0.79) to those done by a single reader (kappa=0.88).

^c Based on 318 clients with complete diagnosis.

Does triage make a difference? Using a test like VILI and providers who have received more in-depth training, triage can greatly reduce the number of women with false-positive screening results who receive treatment unnecessarily. The high PPV of VILI (81%) means that only 19 percent of screen-positive women actually had no lesion and would have been given treatment unnecessarily. The relatively high sensitivity of the triage test for high-grade disease (90% or better) suggests that only a small proportion of women truly needing care are lost at this stage.

Are any cancers missed or treated inappropriately? There were ten invasive cancers identified by biopsy during the project (nine squamous and one adenocarcinoma), plus three identified by subsequent history or treatment (two deaths and one hysterectomy). None of them was treated with cryotherapy. Of these 13 women, seven were identified as suspicious for cancer by the triage test, four were “positive” by triage test and would have been considered treatable by cryotherapy, and two are missing triage results. If colposcopy and biopsy are not available, about one percent of screen-positive patients (or 1 to 2 per 1,000 women screened) might be inappropriately treated with cryotherapy. The main consequence would be a delay (until the one-year follow-up visit) in getting more definitive treatment for their cancer. Even taking biopsies does not guarantee correct diagnosis, since one of the women who died had a negative biopsy after a positive triage test. Based on these data, 92 biopsies would be needed to prevent one missed case of cancer, assuming that all biopsies were accurate and were returned to the facility and that women with findings of cancer could be located.

Quality control for laboratory results. Clients seen before September 2002 had their biopsy and Pap smear specimens sent to Lyon, France, for review by two expert pathologists. Inter-rater agreement between two unique reviewers was assessed using the kappa-statistic. The kappa-statistic shows the proportion of possible agreement achieved after agreement by chance is subtracted. The resulting kappa from comparing the expert diagnoses to the in-country diagnoses shows very low agreement between the expert and the in-country pathologists (biopsy: kappa=0.13; Pap smear: kappa=0.04). Most of the disagreement on biopsy was due to in-country pathologists calling specimens abnormal that experts considered normal (47 of 62 discordant results), while the main areas of disagreement on Pap smears related to overcalling of specimens as low-grade that experts thought normal (47 of 107 discordant results) and determination of ASCUS (41 of 107 discordant results). The rest of the differences were related to stage differences, and relatively few were due to missed abnormalities by the in-country pathologists.

Cryotherapy safety, acceptability, and effectiveness

A total of 155 women aged 30 to 39 years were assessed by colposcopy or biopsy as having cervical lesions compatible with CIN, while 12 additional women were referred to the provincial hospital because the lesions were either suspicious for cancer on colposcopy (2) or confirmed as cancer on biopsy (10). One client who was positive on colposcopy but had conflicting biopsy results was not treated and later underwent hysterectomy. Of those with CIN lesions, 148 (95%) were deemed to be appropriate candidates for cryotherapy (including seven clients who had a lesion extending into the canal to an unspecified depth but were considered by the provider to be appropriate for cryotherapy). Of the seven who were not suitable for cryotherapy, six had endocervical canal involvement of unspecified depth, and one was assessed as having a lesion that was too large. In addition, two women were found to be pregnant at the time of the cryotherapy examination and were advised to postpone treatment until at least six weeks postpartum; one was treated during the exam visit and one was lost to follow-up.

Of the women known to be eligible for cryotherapy, 82 (55%) actually received treatment, while one refused and the rest were lost to follow-up. Of those who were treated, only 23 (28%) received cryotherapy during the triage visit; 54 (66%) were treated some time later (usually after biopsy results were available), and five had unknown treatment dates. Women with cervical lesions appropriate for cryotherapy were equally distributed among the 30 to 34 (46%) and the

35 to 39 (45%) year age groups (age data are missing for 9% of these clients). Based on clinical examination, 13 women (9%) were identified as having cervicitis, one (1%) vaginitis, and one (1%) trichomoniasis. Based on histology, five additional women (4%) were identified as having cervicitis and, based on cytology, one (1%) had bacterial vaginosis.

Is cryotherapy safe? There were no major complications resulting from cryotherapy during the project, based on routine follow-up visit data, on a special follow-up survey done on 22 of the first 25 women treated, and on regular checking with health facility staff. As expected, vaginal discharge was common in nearly all clients receiving cryotherapy. A variety of minor problems were reported, but there is no baseline data on these problems or any comparison group of untreated women, so it is difficult to be sure whether the problems related directly to the treatment. Of the 30 women with a 1- to 3-month follow-up visit, 18 (60%) reported experiencing some pain after cryotherapy that had not been there prior to treatment, while 26 percent noted minor postcryotherapy vaginal bleeding. Five clients reported either pain or bleeding associated with sexual intercourse. Two clients were given antibiotics during the visit. No further complications or side effects were reported at the one-year visit. All six clients who reported a pregnancy and its outcome after their cryotherapy treatment had a live birth without any problems noted.

Is cryotherapy acceptable to women? Most women found cryotherapy to be acceptable. During the early follow-up visits, women were asked about their overall satisfaction with the treatment and in particular their ability to follow the care instructions relating to abstinence. Despite the minor physical complaints noted above, 30 (97%) of the clients with a 1- to 3-month follow-up visit were satisfied with the treatment and all but one indicated that they would encourage others to have cryotherapy if needed. Of the 25 clients who responded to a question about acceptability at one year, 88 percent reported being satisfied while the remaining 12 percent were somewhat satisfied with treatment. All 25 clients had positive responses when asked what they would say to a friend if a health provider recommended treatment.

In the special follow-up survey of 22 women, trained interviewers asked about the acceptability and social consequences of the cryotherapy procedure. Several problems with the hospital counseling were identified, such as women feeling they did not have the opportunity to ask questions or clarify doubts they had before treatment or not fully understanding the informed consent document they signed. These lapses were addressed by refresher training and by providing a flipchart to be sure that all messages were conveyed and women were given a chance to ask any questions. Most found the waiting area comfortable, the examination room clean, and the waiting time acceptable (although it was 1½ hours on average).

Although clients were advised to abstain from sex or to use condoms for at least one month following cryotherapy, nine women (39% of those who attended the 1- to 3-month follow-up visit and responded to the question about abstinence) reported they were unable to abstain for the full period; six of these said they were pressured by their husbands. No clients reported other reasons, such as forgetting the advice or not being convinced of its importance. Data from the special postcryotherapy follow-up study give a similar picture, with nearly half reporting intercourse within one month. However, most of those did abstain for at least three weeks, and half reported using a condom at least some of the time.

Is cryotherapy effective? Although follow-up was incomplete, cryotherapy as performed by nurses was generally effective. Success rates with cryotherapy done by gynecologists have been reported as 86 to 91 percent,¹⁵ but were a little lower (77%) based on our small numbers. Of the 34 women who were examined one year after cryotherapy, one (3%) was assessed by biopsy as cured, 23 (68%) were assessed by colposcopy as cured, and two additional women (6%) were VILI-negative. Of the eight women (23%) with lesions still present (seven were biopsy-confirmed), four had a low-grade lesion and four had a high-grade lesion. Five of these were treated with cryotherapy again. Of the three women not receiving repeat treatment, two were considered ineligible based on their colposcopy findings and one was lost to follow-up. Since treatment is not effective in all cases, it is important to emphasize return at one year to assess treatment success and to repeat treatment or refer if necessary.

Community Mobilization

Community outreach served several critical functions, including building general community support for the new cervical cancer prevention services, letting women know about the need for screening and providing motivational support, and motivating women who missed a follow-up visit to return for needed care. Various monitoring and evaluation activities provide both quantitative and qualitative insights into how feasible various outreach strategies were, how effective they were at both community and individual levels, and other factors that affected women's decisions to seek screening or complete recommended follow-up care.

Mobilizing women and building community support

WKCCPP relied on a variety of community volunteers and government workers to get the message out to women and the community at large.

How active a role can community workers play? MYWO CHWs carried out an impressive array of activities in the first 17 months of the pilot phase (Table 4). Detailed activity data from the expansion phase, when transport subsidies ended, are not available, but clearly dropped off substantially. However, this intense start-up activity undoubtedly played an important role in launching the new service.

In the expansion phase, only limited data on activities are available, especially from the health center CHWs. Of the 12 trained Social Development staff who work in about 30 sublocations, only four reported carrying out any cervical cancer awareness-raising activities. Reported activities for these four individuals were limited to three sublocations and included group talks (28), barazas (16), home visits (48), and clinic talks (9). While barazas were for raising awareness in the general community, the other activities concentrated on reaching women eligible for screening. Although these officers reportedly oversee the activities of hundreds of women's groups and have tremendous potential for raising awareness about cervical cancer prevention, they also have many other responsibilities and have few resources available to carry out their duties. Limited activity levels focused on cervical cancer prevention were, therefore, not surprising. Of the 48 WGLs who were trained, 28 reported engaging in promotional activities such as group talks, personal visits, barazas, and facility talks during the expansion phase.

Table 4. Community mobilization activities carried out during the pilot phase by MYWO community outreach workers.

Indicator/Activity	Activity Totals (n = 43 CHWs)	Avg. Per CHW (range)
Barazas attended	332	7.7 (0–22)
<i>Total number women reached</i> *	3745	87 (0–372)
<i>Total number men reached</i>	9878	229 (0–948)
Community leader meetings held	808	18.7 (0–77)
Women’s groups contacted	463	16.0 (3–29)
<i>Number eligible women reached</i>	4,245	98.7 (0–392)
Church group meetings attended	284	6.6 (0–30)
<i>Reported number women attended*</i>	6997	167.6 (0–492)
<i>Reported number men attended</i>	2,870	68.3 (0–223)
Initial visits made to registered women**	1,586	36.9 (2–109)
Hours spent conducting group activities	6,710	156.0 (4–459)
<i>Avg. hours per month</i>	--	9.2 (0.2–27)
Hours spent conducting initial visits with women	2,987	69.5 (2–176)
<i>Avg. hours per month</i>	--	4.0 (0.1–10.4)
Women referred for screening	2,873	66.8 (11–211)
Referred women who attended screening during pilot phase	1,024	20.0 (1–86)
<i>% of all those referred</i>	35.6%	36.9% (4–100%)

* Not necessarily in eligible age range.

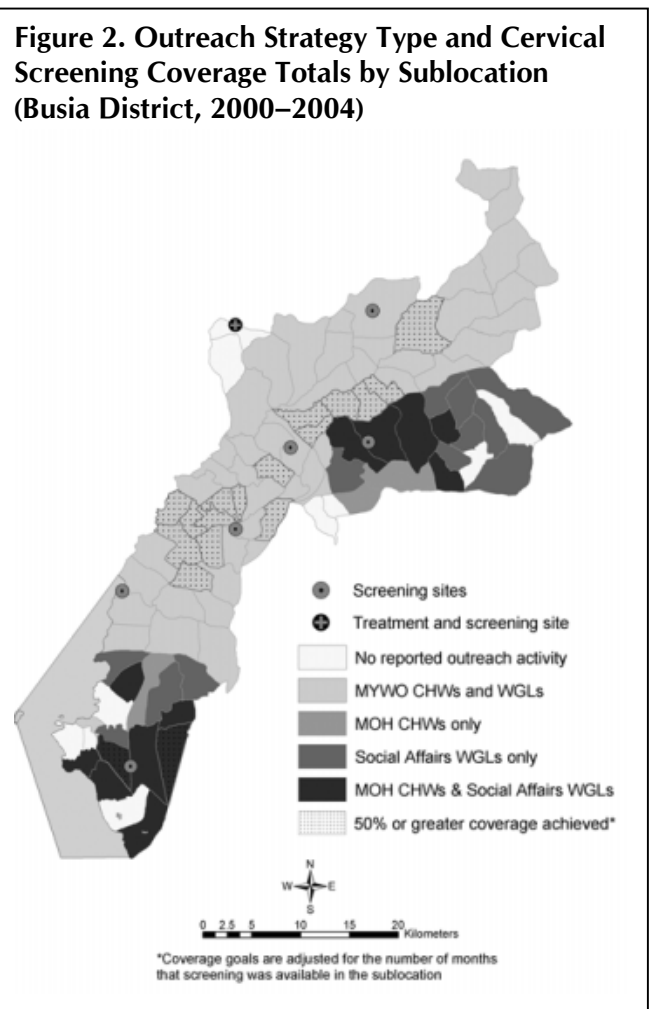
** Registered women, regardless of how they were recruited, typically received a personalized visit from a MYWO CHW to further explain the cervical cancer prevention activities.

Table 5. Screening coverage achieved, by outreach strategies.

Indicator	Outreach Strategy				
	MYWO	MOH CHWs Only	Social Affairs WGLs Only	MOH CHWs & SA WGLs	No Activity
Coverage area (no. sublocations)	61	2	15	13	9
Eligible women (average per sublocation)	212	309	251	250	326
Time-adjusted coverage goal* (average per sublocation)	107	65	53	57	118
Women screened (average per sublocation)	29.7	5.5	2.4	8.1	1.6
Percent of time-adjusted coverage achieved (average per sublocation)	32.6%	8.1%	5.5%	19.8%	3.0%
Percent of sublocations achieving 50% or more of time-adjusted coverage goal	26%	0%	0%	15%	0%

* Time-adjusted coverage goals are calculated by dividing the annual target (15% of total eligible population) by 12 to get a monthly target and then multiplying by the number of months that screening was available.

Did the different outreach strategies have any effect on women's attendance at screening? Screening coverage varied considerably among the sublocations, ranging from none to as high as 94 percent. Screening percentages among the 100 sublocations averaged a little over 23 percent. There is some evidence to suggest that the different outreach strategies introduced in each sublocation had an effect on screening coverage levels. Time-adjusted coverage totals were based on annual targets of 15 percent (to get cumulative 75 percent coverage in five years), adjusted by the number of months of project activity in a given sublocation. Sublocations shaded with dots (see Figure 2 showing time-adjusted screening coverage totals at the sublocation level) represent the more successful areas where at least 50 percent of the time-adjusted screening target was reached. Most of these successful sublocations are located in areas where MYWO-trained CHWs and WGLs worked during the pilot and expansion phases. Two others (lower bottom right of Figure 1, page ii) were in areas with MOH CHWs and Social Affairs WGLs.



Even after adjusting for the longer period during which they were active, MYWO CHWs were more successful than any of the other outreach strategies in the average percent of eligible women screened per sublocation (32.6%, versus 3-20% among the other strategies) and the proportion of sublocations achieving at least half their time-adjusted target (see Table 5). The nine sublocations with no organized outreach activity experienced very low levels of screening.

The high rate of screening coverage achieved by MYWO in the first year (46 percent of their time-adjusted goal) was probably due to usual start-up enthusiasm and to monthly travel stipends given to CHWs then, which no doubt enhanced outreach capacity. When travel funds were no longer available after March 2002, screening coverage dropped by about half. MOH outreach workers and WGLs affiliated with the Social Affairs office worked without any subsidies and little supervision, which may account for their lower success rates.

Factors other than the strategy itself may account for some of the sublocation differences. For example, most successful sublocations cluster closer to health facilities (Figure 2) and along major roads that lead to health facilities and had a lower density of eligible women. Further statistical analysis also showed that particular sublocations with better screening coverage had more intensive outreach activity (regardless of strategy type) as measured by the total number of outreach workers reporting activity in that sublocation.

Is a supportive environment necessary? Early in the pilot phase, misinformation about the new cervical cancer prevention services began to circulate in the project communities, with potentially devastating effects on the new service. Rumors equating the screening and treatment services to devil worship (because of the project's red and blue logo), beliefs that body parts were being removed or cut, and fears that the screening test was really for HIV sprang up in the district. As each of these rumors emerged, CHWs notified their supervisors, who then made extraordinary attempts to find their source, to speak to prominent leaders about them, and to work with them to dispel the negative rumors with correct information. CHWs were also briefed on how best to respond to the rumors. Civic leaders and clerics continued to play key roles to correct misinformation that arose thereafter about the cervical cancer prevention program.

What factors affected women's decisions to be screened? Answers to this important question come from formative research conducted during the preparatory phase, from analysis of the CHW activity data, and from a special study that examined factors affecting screening status among screened and unscreened women carried out at the end of the project. Opinion leaders interviewed during the formative research highlighted three important influencing factors:

1. Low level of existing knowledge and understanding of reproductive health and disease.
2. Stigma and belief in negative rumors/myths/fears.
3. Lack of financial and/or emotional support from male partners.

Women and opinion leaders also felt that women in this age range need complete and accurate information *before they arrive at the clinic*. Women also wanted assurance that they would actually be seen when they arrive after a sometimes long and difficult journey and that they would be treated well by those who saw them. CHWs reported that women who are turned away, or think that they will be turned away, are not likely to go (again) without additional motivation. Some participants felt that gender (male providers) would be a problem among very religiously conservative communities.

A statistical analysis of MYWO CHW activities using correlations and a general linear model found that recruitment through church groups and women's groups were the most effective outreach activities for contacting and referring women in their 30s for screening, and that church group venues appear to be good places for CHWs to meet women's group members and establish further inroads to other women's groups. Although this analysis could not show a clear relationship between increased referrals and women's actual participation in the screening program, the importance of these group venues was verified in interviews with individual women (see below). Individual CHW characteristics such as age, sex, social standing in the community, the number of hours spent carrying out different kinds of outreach activities, and the number of revisits made to referred clients seemed to have little effect on screening participation.

In early 2004, project staff aided by MYWO outreach workers carried out a randomized, case-control study to identify key factors influencing women's participation in the WKCCPP cervical screening program (see Appendix 15). Women who had been registered by community outreach workers and exposed to cervical cancer promotional activities made up the eligible study population. Both screened and unscreened women (184 and 160, respectively) were randomly selected to participate in the study. Semi-structured interviews were carried out by trained

researchers. The interview covered a number of topics that had been identified in other studies as factors influencing a woman's decision to seek screening or had been identified as being important during the course of the project. They included socioeconomic and demographic information, health-seeking behavior, health knowledge and beliefs in preventive care, sociocultural norms, service delivery and quality of care, and the influence of negative or false rumors about screening services. Statistical models were developed using logistic regression analysis. Significant independent effects were found despite variation seen in the data.

The strongest predictor of screening status in this Women's Participation Study was the number of screened women that a woman knew; the odds of a woman being screened increased 1.7 times for each extra woman she knew (up through five, and leveling off after that) who had been screened (OR 1.7; 95% CI: 1.4–1.9). Where women first heard the screening message also had some effect on the likelihood they would actually go for screening. Although numbers were small, women who first heard about screening at a health center (also known as “in-reach”) were most likely to go on and get screened (OR 7.1; 95% CI: 2.2–22.9). Among the various outreach approaches, church or school group meetings (OR 2.1; 95% CI: 0.98–4.5), and possibly women's group meetings, were at least as effective venues as home visits, and possibly more so. The odds that a woman was screened diminished by nearly half (OR 0.59, 95% CI: 0.35–0.98) if she had heard rumors of women being turned away by providers because they were too busy. Not surprisingly in this impoverished rural setting, the odds that a woman was screened also dropped by nearly half if the level of travel difficulty (in terms of time and cost) was rated as high (OR 0.59, 95% CI: 0.35–0.98).

Motivating women who missed a follow-up visit to return for needed care

Many of the same barriers and enabling factors that influence a woman's decision to seek screening apply to follow-up care: fear and stigma associated with cancer, lack of financial resources, discomfort with intimate examinations, unsupportive partners, confusion of cancer with HIV/AIDS, having confidence that treatment received will take care of the problem “once and for all,” and assurance that women who go to the health facility will in fact be seen.

Difficulties outreach workers faced when doing mobilization activities

The most important challenge that outreach workers faced were the costs involved with traveling throughout the coverage area to carry out recruitment and follow-up activities. This was an ongoing concern throughout the project. Additional issues cited were: not having educational flipcharts to inform and educate, need for more training on difficult health issues, feeling helpless to change the understaffed health facilities, erratic hours, lack of equipment and supplies, wishing there were more resources to give poor women to help pay for their transport (although many reported they did), and better supervisory oversight. Additionally, some outreach workers felt that HIV/AIDS and other STIs were an equally important priority for women in their communities. In response to this last point, additional technical training was provided to some outreach workers on how to make referrals to people who sought advice in these important health areas.

Program Outcomes

There are both outcome and process indicators to be evaluated in considering overall program success. Because of the small area and the short time duration, WKCCPP focused on process outcomes rather than health outcomes related to disease incidence and cancer mortality.

Coverage, program quality measures, capacity development, system design, and economics were key issues for evaluation. Specific research questions included:

- What percent of the eligible population was screened during the project?
- What were the main barriers to coverage?
- Is 30 to 39 years an appropriate age range for screening?
- To what extent did women complete required follow-up care?
- What was the quality of care and what mechanisms were useful in maintaining it?
- What additional burden did the new service put on staff at each level?
- What were the clinical and community costs?
- What mechanisms are feasible for financing these costs?

Screening coverage: achievements and barriers

The original goal of reaching 75 percent of eligible women within the life of the project proved not to be feasible. When we adjusted the goal to 15 percent of eligible women per year (with the ultimate target of reaching 75% within five years), some sublocations came considerably closer to achieving it. In the three pilot divisions approximately 16 percent of eligible women were screened, while in the two expansion divisions where services were available for just 17 months only 3 percent of eligible women were screened. Rates of screening fluctuated widely, increasing at times of training sessions and dropping off at times of natural disasters (droughts in 2002 and floods in 2003), national elections, annual leave periods, and socioeconomic crises (the minibus strike). As noted in the findings from the Women's Participation Study (above) and from anecdotal reports from supervisory visits, a major factor in the low coverage was the general unavailability of sufficient staff in health facilities (due mostly to unfilled positions and absences for training or leave) such that clients were either turned away or asked to wait for long periods while acute care was provided first, practices that were recounted to others and dampened the interest of women in attending.

Screening age

For this project screening was limited to women 30 to 39 years old, because resources were scarce and there were concerns that women in their 40s would be more likely to have cancer, rather than precancer, and therefore need advanced treatment that was not easily available. Based on our findings that only ten women (0.4%) had cancer and many women even in the upper 30s had only low-grade lesions, it seems reasonable to extend the screening age upwards into at least the lower 40s, where there will still be many easily treatable precancers.

Completion of postscreening and posttreatment follow-up care

Because it was not possible to offer treatment at all screening sites, we were concerned about women's willingness and ability to travel to the district hospital for triage and treatment. In fact, 70 percent of screen-positive women did manage to get to the hospital for further care within 3 months of their screening visit. As discussed above, reports from health workers and community outreach personnel suggest that the main reasons for women failing to follow up after a positive screening test were travel cost, fear about cancer or about the treatment, and lack of partner support.

Of the 49 women who received cryotherapy at least 3 months before the end of the project, 31 (63%) returned for at least one supportive visit 1 to 3 months after treatment to check for any complications or complaints. Of the 45 women eligible for a one-year posttreatment examination at the time of data analysis, 34 (76%) returned to check for treatment success, many after special outreach efforts. Better mechanisms for tracking and reminding women to attend, especially for the one-year visit to assess treatment success, are still needed.

Maintaining quality of care

Regular supervisory assessments of facility and staff capacity demonstrated that using supervisory checklists for both facilities and providers both simplifies and standardizes the assessments by supervisors at each facility and with each provider. They also serve as helpful reminders of areas that need strengthening, allowing supervisors to follow up on problematic areas. For example, in two supervisory visits in 2004 using the most current checklists, recordkeeping was the most problematic topic (incomplete or absent monthly VIA reports, incomplete information in the client register), followed by shortages of equipment (torch) and supplies (gloves) and counseling deficiencies. Minor revisions to the current checklists are still needed in order to adequately capture quality of counseling for each facility because the current checklists only capture whether or not counseling was completed.

Based on the photo quizzes used throughout the project to measure provider-screening skills during supervisory visits, there was a gradual drop-off in scores from 79 percent correct photo identification in January 2001 to 59 percent correct in April 2004. The mix of experienced and inexperienced screeners may influence these average scores.

Feedback provided by clients who returned after treatment suggests a high level of satisfaction with their screening and treatment experiences. Overall, at 1 to 3 months after treatment, 29 (94%) said they would recommend screening to others, and 22 had already recommended screening to a total of 142 family or friends. At one year, all clients who responded to the satisfaction question reported being satisfied (92%) or somewhat satisfied (8%) with the screening examination. All 26 clients also reported that they would recommend screening to others.

Capacity development and burden of new service

Training of general clinical staff, community staff, and senior specialists increased district and provincial cervical cancer prevention capacity to pursue and maintain an integrated prevention program. At the district level, between two and eight clinical officers and/or nurses from each health facility participating in the project were trained in VIA and VILI. At the district hospital, four providers were also trained in VIAM, VILI, and cryotherapy for suitable lesions. The providers at the primary health facilities and the district hospital are capable of providing on-the-job training to inexperienced clinic staff at their facility or expanding the service to new facilities as they are transferred. Since the Busia district public health nurses responsible for supervision were also trained in prevention techniques and supervision of screening, triage, and treatment, they are now capable of supervising trained clinical staff and of helping on-the-job trainees to advance their skills. A summary of key steps in screening was developed and was provided to all trainees (see Appendix 16). VIA and VILI photo quizzes were developed to enhance the capacity of supervisors to effectively assess provider skill levels in the absence of clients.

Through training at the community level, 73 government and volunteer outreach workers, 79 women's group leaders, and 16 supervisors learned about cervical cancer prevention messages and how to pass them on via community meetings, women's group meetings, funerals, church meetings, and one-on-one visits. These community outreach workers were supervised either through the health facilities, MYWO, or the office of Ministry of Gender, Sports, Culture, and Social Services. Many of these supervisors participated in the initial training and are capable of training others using the curriculum that was developed. At a higher level, these supervisors are also capable of advocating for cervical cancer prevention in their communities and effectively transmitting prevention messages.

Senior-level clinical capacity was strengthened in three provinces (Western, Nyanza, and Rift Valley) and at the national referral hospital in Nairobi. At least one gynecologist from each province was trained in VIA, VILI, colposcopy, cryotherapy, and appropriate follow-up methods for difficult cases. Although primary screening only occurred at health facilities in one province, the other two provinces now have experts who can advocate for cervical cancer screening programs in their province and are able to effectively manage difficult precancer cases that report to their provincial facilities. In addition, Nairobi now has two master trainers experienced in using the VIA and VILI curriculum to train additional trainers and health providers.

Because the new screening service was integrated into existing services, it did not create a substantial new demand on staff. The need to pull staff out for initial training is an inevitable start-up burden, but was kept to a modest level (one week). At the levels of coverage achieved during the project, the average number of women screened per month at each health center was just 22 in the pilot phase and 7 in the expansion phase. At the target level of 75 percent in five years, each health center in Busia would need to screen about 48 women per month. Recruiting just three women per month from each of the 100 sublocations in the district would achieve the program goal. In the current crisis of understaffing, preventive measures like cervical cancer screening may be perceived as a burden unless staff fully understand the rationale for it, including the level of disease impact and the ultimate cost-benefit from prevention. District hospital staff performing triage, treatment, and referral seemed to have had no difficulty coping with the service demands during the project. At an estimated screen-positive rate of 14 percent and 80 percent actually attending for triage, the district hospital could expect to see about 32 women per month at the target coverage level. This seems to be a manageable burden, which will be offset within a few years by the reduction in women coming for outpatient and in-patient care for cervical cancer. Since supervision for the new service can be easily carried out by those who supervise other reproductive health services, any incremental burden there is minor.

Economic analysis

Detailed information on methodology and assumptions for the economic analysis is provided in Appendix 17, along with Tables 17-1 and 17-2.

Total incremental costs of cervical cancer screening and treatment. Table 17-1 presents the total costs for both the pilot phase and the total project period (pilot and expansion phases) when start-up costs are included for advocacy and awareness raising, materials development, and clinical training. The total incremental cost during the pilot phase (2 years) was US\$10,031 for a total of

1,634 women screened. For the total project period (3-½ years), the total costs were US\$11,357 for 2,379 women screened.

The average *cost per woman screened* was calculated by dividing the total costs of screening and treatment by the number of women screened. The average cost per woman screened was US\$6.00 in the pilot phase, and this decreased to US\$4.77 for the whole project period. During the pilot phase, 66 percent of the total program costs were for one-time start-up activities related to information, education, and communication material development and initial clinical training in VIA, colposcopy, and cryotherapy. Over the entire project period, these fixed one-time costs are distributed over a larger number of beneficiaries, reducing the average cost per woman screened. At the health center level, the average cost of consumable supplies was US\$0.38 per woman screened. These costs were nearly covered by a user fee of US\$0.32 (KSh.25).

The average *cost per woman with disease detected and treated* was calculated by dividing the total costs of screening and treatment by the number of women treated. During the pilot phase, 56 women were treated with cryotherapy at an average cost of US\$179 per woman. During the total project period, 73 women were treated at an average cost of US\$156 per woman.

Table 17-2 presents the total costs for both the pilot phase and the total project period in the absence of start-up costs. These data estimates are useful for evaluating the capital and recurrent costs for cervical cancer prevention services once a program is up and running. These are the costs that are most likely to be incurred and funded locally. The average *cost per woman screened* is US\$2.07 during the pilot phase and decreases to US\$1.84 over the course of the project. The average *cost per woman treated* is US\$60 for both the pilot phase and the overall project period.

Cost Profiles. Tables 17-1 and 17-2 also provide information on the shares of each cost component as part of total incremental costs. When start-up costs are included, capital costs account for 15 percent of total costs. The highest share of capital costs is for recurrent training at both the health center and district hospital. Recurrent personnel and supply costs for screening and treatment comprise 19 percent of total incremental costs. Screening at the health center accounts for 65 percent of total recurrent costs. Table 17-2 provides a clearer picture of cost shares for service delivery. For the total project period, capital costs comprise 37 percent of total incremental costs. For the remaining recurrent costs, salaries and supplies at the health center level account for 67 percent; triage tests at the district hospital comprise 14 percent; and treatment at the district hospital accounts for over 17 percent.

Is cervical cancer prevention cost-effective? Screening and treatment for cervical precancer is a cost-effective intervention to save women's lives. Total incremental costs range from US\$4.77 to US\$6 when considering all start-up costs, and range from US\$1.84 to US\$2.07 when focusing on service delivery costs alone. The average cost per woman screened is sensitive to the number of women who are screened. The costs associated with resource-intensive activities, such as raising awareness, developing IEC materials, and initial and recurrent clinical training sessions are spread over a larger number of women, bringing the average cost down.

Similarly, treatment costs range from US\$156 to US\$179 per woman identified and treated, depending on the number of women reached. Focusing only on service delivery, the cost is

US\$60. Average screening costs will be reduced faster than treatment costs in a program that reaches high coverage rates.

A key to increasing coverage is community mobilization to raise awareness of the risks of cervical cancer and to successfully recruit women to visit their local health center to receive screening. These costs are not included in this analysis.

Sustainability

The model has several factors that enhance its sustainability, but there are also challenges (even after start-up training and other inputs are in place) that could undermine its ability to maintain momentum and achieve its full potential. The key elements that should enhance its ability to be sustained are:

- Integration within the existing primary health care services.
- Dependence on nurses rather than specialists.
- Low cost, much of which can be recovered from women at the usual fee levels.
- Reliance on easily obtainable supplies.
- Availability of proven learning tools, counseling materials, and sample record systems.
- Good evidence about important local community concerns and effective outreach strategies.
- Existence of local expertise and master trainers.
- Commitment within MOH and local professional community to prevent cervical cancer.

On the other hand, constraining factors that could jeopardize the program's sustainability will require careful monitoring and corrective action. They include:

- The shortage of functioning community outreach mechanisms to ensure that systematic recruitment continues to identify new, previously unscreened women in the eligible age group.
- Inadequate staff in health centers, causing preventive care to be sidelined in favor of acute care demands and women to be turned away or face long waits when they come for screening.
- Inadequate clinical supervision, making it difficult to ensure that screening and treatment skills are maintained and protocols are followed.
- Poor information on disease burden and program effectiveness (to help in advocacy and resource-allocation decisions).
- The shortage of expertise at provincial level to deal with complicated cases that will increasingly be identified as screening expands.

Most of the constraints reflect general weakness in the health infrastructure; all efforts to address those weaknesses would benefit both the general health system and especially the cervical cancer prevention effort, making it more effective and sustainable.

National Strategy and Guidelines

Early in 2003 the MOH announced its support for developing a national five-year Cervical Cancer Prevention Strategy. They established several working groups and invited WKCCPP

partners to join in the planning process. Three representatives from the MOH made a site visit to the WKCCPP in Busia early in 2004 to observe the model and discuss with local staff their experience and recommendations. PATH contributed to the drafting of the strategy document and co-hosted with the MOH a one-day meeting of national experts in February 2004 to reach consensus on appropriate guidelines for a national program. The MOH adopted several key elements of the WKCCPP clinical approach, including visual screening (VIA and VILI) at primary care level, triage assessment (based on VILI) and cryotherapy treatment by nonphysicians at district level, and referral to provincial level for advanced care like LEEP, surgery, and cancer staging. Basic data for monitoring will include (1) the number of women screened, (2) the percent who are screen test-positive, (3) the percent of triage test-positive women who receive appropriate treatment, and (4) the percent treated who attend for one-year follow-up. Appropriate strategies for informing eligible women about screening will be left to district authorities to determine. The MOH has decided on a phased approach that builds on the three hubs—Western Province, Coast Province, and Nairobi—where trained gynecologists are already in place to manage complicated cases and oversee the screening and treatment program.



Conclusions and Recommendations

WKCCPP clearly demonstrated that cervical cancer prevention services based on visual inspection and cryotherapy performed by nurses can be established and sustained in rural Kenya with relatively modest start-up requirements and support. Our results, when added to other local and international experience, provide a useful body of evidence for Kenya and possibly for other rural African settings to draw on.

Clinical Care

The model tested here included screening, triage of screen-positive women to reduce false positives, treatment, follow-up, and referral to provincial level of those needing specialist care. Although the model led to successful identification and treatment of women with precancerous cervical lesions within local resource constraints, there were clear trade-offs as well. We have good evidence for the following:

- *Using VIA to screen* women in this age group achieves reasonable sensitivity (better than a single Pap smear) and is feasible and affordable, but it leads to 15 to 20 percent of women being referred to the district hospital.
- Centralizing triage and *treatment at the district hospital level* (or higher) is efficient and probably enhances quality of care, but it risks loss to follow-up (30% in WKCCPP).
- Given that a second visit was necessary for screen-positive women, adding *VILI as a triage test* greatly reduces the number of false-positive women, while missing only a few real cases.
- *Cryotherapy done by specially trained nurses* is safe, with very few major complications (none during WKCCPP) and side effects that are acceptable to women if they receive appropriate counseling.
- Doing *cryotherapy without performing biopsies* is safe, with cancer rarely being missed.

We have less complete data for the following conclusions due to shorter experience or smaller numbers, but in some cases there is also international data to support our findings.

- *Combining VIA and VILI for screening* constitutes an easier and more accurate test.
- Cryotherapy is generally effective (about 77% based on our small numbers), but *one-year follow-up is critical* since failures can occur. Repeat cryotherapy can address most of the failures.

Community Mobilization

Community outreach is a critical component of a screening program, especially in the early start-up years when awareness is low. As a result of the WKCCPP experience we know more about how to do this effectively, but plenty of challenges remain. This research has shown that raising the general level of awareness about the need for cervical screening in communities is an important first step for increasing the demand for services, but cannot in itself guarantee good coverage results. Other factors have a significant effect on whether a woman actually participates in a screening program:

- *Knowing other women who have been screened* is a powerful determinant in a woman's own decision to be screened and may even offset other barriers, so screened women should be encouraged to participate in outreach efforts, especially by speaking to other women in groups they belong to.
- Building up knowledge and *support among community leaders* is critical for creating an environment that helps women overcome the natural barriers to screening and that addresses threats like rumors promptly and effectively. Personal visits to leaders and barazas are good approaches for this purpose.
- An outreach strategy that works *through church, school, and women's group networks* can effectively and efficiently reach sufficient numbers of eligible women with the required information on why and where to go for screening, especially if it is organized to track systematically those who are eligible and those who have already been screened.
- *Women's group leaders*, especially if they have been screened, can be especially effective as promoters.
- Reaching eligible women who are already at a health facility ("*in-reach*") is one of the most effective strategies, since these women have already overcome the difficulties of getting to a facility and health workers are seen as credible sources of health information.
- Since travel is a barrier to many women, it is critical that women who do attend for screening *receive timely care and are not turned away*; reports of women being turned away have ripple-effects that may discourage many other women from attending.
- *Outreach workers can be effective* with relatively brief training (one to two days) and appropriate job aids; their main challenges are travel costs and systems for tracking contacts.
- *Incentives need not be monetary*; preferential services at health facilities for volunteers and their families may be sufficient.
- According to women, *desirable qualities of those doing outreach* are that they speak the local language; are sociable; and are perceived as well trained, skilled, knowledgeable, and empathetic.
- The message about cervical cancer prevention can be *integrated with other health and development activities* in the community.

There were several unresolved issues about community mobilization, such as how to support travel costs of outreach workers, whether outreach workers can also provide reminders about follow-up care, and how to support women who have untreatable cancer. Each community will have a different configuration of outreach resources (government workers from health and other sectors, as well as NGOs) and individual champions, so there should be flexibility to build on what is available.

Program Issues

Establishing clinical services alone will not achieve the desired disease and mortality reduction unless several critical components are in place:

- Effective mechanisms for mobilizing women to take up the service.
- Basic health services with adequate staff and supplies.
- Adequate supervision to ensure quality of care is maintained and staff are complying with program guidelines such as target age group and recordkeeping.
- Specialist services at provincial level to manage complicated cases.
- Key indicator data to enable effective program management.

WKCCPP experience confirmed several features of the model program:

- *A coverage target of 75 percent* of eligible women screened once over five years does not place too heavy a burden on health facilities (e.g., about two to three women per day in each facility) or on outreach workers (two to three women per month from each sublocation).
- *Women in their 30s are the most appropriate age group.* There is no need to screen women younger than 30 years, since many women even in their upper 30s had only low-grade lesions; it seems reasonable to extend the screening age upwards into at least the lower 40s where there will still be many easily treatable precancers.
- Both clinical care and community mobilization for cervical cancer prevention can be *integrated into other programs* to enhance access and efficiency.
- A cervical cancer prevention *client card* is useful (as compared with just writing in a general record), since it helps the woman remember her history and know when to return and assists different referral levels in tracking her findings and subsequent action. The cervix diagram is useful for communicating clinical information to referral levels.
- The *recurrent cost of screening and treatment services is affordable*, although transportation may be unaffordable for some women.

There are several program issues that are not fully resolved and require further attention as national scale-up proceeds:

- Effective counseling for women (and where possible, their partners) will be needed to ensure that screen-positive women go on to the referral facility where triage and treatment are provided.
- Key indicators should be integrated into the health information system so that the program can be routinely monitored for quality and efficiency.

- Ways to maintain clinical skills like VILI, whether through photo quizzes or periodic refresher training, should be carefully validated and monitored.
- Referral to provincial level for complicated cases, suspected cancer diagnosis and staging, and palliative care is still not working well, primarily because of the costs for transport and treatment, which women find difficult to manage. Mechanisms to mobilize family and even community support for these women should be developed.

At national, provincial, and district levels, through WKCCPP and other efforts, there is now a critical mass of clinical capacity, training resources, and program experience that should be sufficient to guide and sustain a cervical cancer prevention service in Kenya. The need is evident, a workable model has been validated in WKCCPP, and women have shown they are willing to participate in the program. With commitment at national and local levels, an affordable and effective cervical cancer prevention service could be phased in over the next five to ten years, and thousands of women's lives could be spared.



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