JHPIEGO An Affiliate of Johns Hopkins University
A GLOBAL LEADER IN IMPROVING HEALTH CARE FOR WOMEN AND FAMILIES

Safety, Acceptability, and Feasibility of a Single Visit Approach to Cervical Cancer Prevention: Results from a Demonstration Project in Ghana

Ridge Hospital, Accra

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FOR THE

Ghana Cervicare Group

November 2004

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JHPIEGO, an affiliate of Johns Hopkins University, builds global and local partnerships to enhance the quality of health care services for women and families around the world. JHPIEGO is a global leader in the creation of innovative and effective approaches to developing human resources for health.
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ABBREVIATIONS AND ACRONYMS

CECAP	Cervical Cancer Prevention Program
CIN	Cervical intraepithelial neoplasia
DMPA	Depot-medroxyprogesterone acetate
GHS	Ghana Health Service
HPV	Human papillomavirus
IUD	Intrauterine device
LEEP	Loop electrosurgical excision procedure
MC^3	Multidisciplinary Cervical Cancer Care Group
MOH	Ministry of Health
Ob/Gyn	Obstetrician/Gynecologist
PID	Pelvic inflammatory disease
SAFE	Safety, acceptability, feasibility, and program effort
SCJ	Squamocolumnar junction
STI	Sexually transmitted infection
SVA	Single visit approach
VIA	Visual inspection with acetic acid
WIRB	Western Institutional Review Board

PREFACE AND ACKNOWLEDGMENTS

From January 2001 to the present, JHPIEGO's Cervical Cancer Prevention Program (CECAP), along with colleagues from the Ministry of Health (MOH), Ghana Health Services (GHS) and Korle Bu Teaching Hospital of Ghana Medical School worked collaboratively to assess an alternative approach to cervical cancer prevention. We thank the MOH and GHS, and express special gratitude to Henrietta Odoi-Agyarko, Deputy Director of Reproductive Health/Family & Child Health Unit of the GHS, for her tireless advocacy on behalf of cervical cancer prevention in Ghana.

Ridge Hospital nurse midwife service providers (Gertrude Osikafo-Anteh, Mavis Apatu, Mary Imbeah, Desiree Opku) and Follow Up Nurse (Edith Amenudzi) carried out the fieldwork with inspiring commitment and enthusiasm. Clinical supervisors from Ridge Hospital (Edward Attoh, Alexander Laryea, and Satya Sackey) and Korle Bu Teaching Hospital (Nelson Damale and Kwabena Nkyekyer) also performed with dedication. Local project management staff (Sylvia Deganus, Project Manager, and Sydney Adadevoh, Project Director) built strong links between project and local health institutional structures, and led the project admirably. Amanda Adu-Amankwah coordinated all aspects of project activities with great professionalism. Joy Reimmer and Salome Tete provided invaluable administrative support, and Myra Mensah assisted with manual data cleaning. We thank Abigail Kyei, the JHPIEGO Country Representative in Ghana, as well as the entire JHPIEGO/Ghana team, for all of their assistance.

The Health Research Unit of the MOH was instrumental in assisting JHPIEGO to manage data for this project. We thank John Gyapong and his data management team (Amanuah Chinbuah, Jane Amponsah, Dominique Antweam Kobinah, Cecilia Amoakwao, and Dela Osei-Semackor) for their expert technical support.

We extend our gratitude to members of our Technical Advisory Group (Henrietta Odoi-Agyarko, Ben Foleson, Gladys Kankam, Baffour Awuah, Amanuah Chinbua, Kwabena Nkyekyer, Verna Vanderpuye, and Kwame Wiredu) who not only guided project implementation, but also crafted recommendations to the MOH that led to the incorporation of the single visit approach using VIA and cryotherapy into the National Reproductive Health Service Delivery Guidelines. Members of the Rotary Club of Accra-Achimota District 9100 and the Rotary Club of Oakland District 5170 recognized the importance of cervical cancer prevention, and dedicated generous support to activities during the rural phase of this project (described in a forthcoming report). Most important, we owe a debt of gratitude to the women, men and their families who participated in this project.

Finally, we thank our JHPIEGO/Baltimore colleagues: Noel McIntosh for overall program guidance; Sarah Slade for training and clinical input; Sapna Sharma for project coordination; Karen Mazziott for financial management assistance; Saifuddin Ahmed for statistical analysis; Sonia Elabd and Deborah Brigade Raynor for training materials assistance; Victoria Robinson for administrative support; and Mark Fritzler for equipment support.

This project was funded by a grant to JHPIEGO from the Bill & Melinda Gates Foundation, through the Alliance for Cervical Cancer Prevention.

EXECUTIVE SUMMARY

A demonstration project to assess a single visit approach (SVA) to cervical cancer prevention was implemented in Ghana from March 2001 to July 2003. The SVA approach links visual inspection of the cervix with acetic acid (VIA) with an offer of immediate treatment or referral, as indicated. The objective of this demonstration project was to assess the safety, acceptability, feasibility and programmatic effort (SAFE) of this approach.

VIA has been established as a viable testing option for low-resource settings (Belinson et al.; Cecchini et al.; Denny et al.; JHPIEGO/RTCOG 2003; JHPIEGO/University of Zimbabwe 1999; Kitchener et al.; Londhe et al.; Megevand et al.; Sankaranarayanan et al.; Slawson et al.; Wesley et al.). Cryotherapy was selected as the treatment of choice for this project because it: 1) has a cure rate comparable to other commonly performed procedures (Andersen and Husth 1992; Mitchell et al. 1998; Nuovo et al. 2000); 2) is easy to learn, does not require electricity, requires few consumables, and has a long history in the scientific literature of low complication rates (Cox 1999; Nuovo et al. 2000); and 3) has an established, safe, and effective performance record with non-physicians in developed countries (Morris et al. 1996).

The project was implemented in a phased approach, beginning in an urban, and then expanding to a rural, setting. The first phase of this demonstration project was implemented in an urban regional hospital, located in the capital city, Accra. Beginning the project in an urban center helped ensure the presence of a functional referral network for cases requiring advanced diagnosis and management prior to commencing screening services. The second phase of this demonstration project, involving expansion of services to a rural site, will be described in a subsequent report.

The project protocol required that test-positive, treatment-eligible women were offered immediate cryotherapy, and counseled about the benefits, potential risks, and likely side effects of treatment. Women ineligible for treatment, that is, whose lesions exceeded 75% of the cervical surface area, or who had suspect cervical cancer, were referred. Data measuring safety, acceptability and feasibility of the single visit approach were collected.

During the 18-month recruitment period at Ridge Hospital, 3,665 women were tested for cervical precancer using VIA. The overall VIA test-positive rate at Ridge Hospital was 13.2%. Among test-positive, treatment-eligible women for whom data are available, 70.1 % accepted the offer of immediate cryotherapy. In total, 439 women accepted the offer of cryotherapy and of those, 76.8% returned for their first followup visit. There were no major complications, and fewer than 6% of those treated returned to the project facility for any perceived problem. Only 4% of those treated required any management other than reassurance for side effects. Both VIA and cryotherapy were highly acceptable to women—more than 98%were satisfied with the experience—and, 1 year after treatment the squamocolumnar junction (SCJ) was clearly visible for the majority of the women who returned, yielding a 1-year VIA test-negative rate of 96.7%.

A single visit approach linking VIA testing with the offer of immediate treatment (or referral) of test-positive cases is safe, acceptable and feasible in low resource settings such as Ghana. This report describes the key results of this demonstration project involving an alternative, field-based, resource-appropriate approach to cervical cancer prevention.

INTRODUCTION

BACKGROUND

Worldwide, cervical cancer remains a pervasive public health problem because access to screening and treatment of precancerous lesions is not widespread (Pisani 1998). Cervical cancer is the second most common cancer among women globally. Each year there are approximately 493,200 new cases of cervical cancer— almost 80% of which occur among women living in developing countries—and more than 200,000 women die of the disease (Ferlay et al. 2004). The vast majority (99.7%) of cases are associated with infection of one or more types of human papillomavirus (HPV), which is sexually transmitted (Walboomers et al. 1999). HPV first enters the cells covering the cervix and then slowly causes changes that, with time, can result in cancer. Although exposure to oncogenic strains of HPV generally occurs at the time of sexual initiation, invasive cancer may not develop until 10 to 20 years later.

Cervical cancer screening aims to detect and treat preinvasive precursor lesions, thereby preventing progression to invasive cancer. The natural history of cervical cancer includes a period of 10–20 years when precancerous lesions can be present. Effective testing and treatment programs can reduce the burden of cervical cancer. Cytology-based cervical cancer screening is considered at least partially responsible for the significant decline in incidence and mortality of invasive cervical cancer in the last few decades in some developed countries (Kitchener and Symonds 1999; Parkin and Sankaranarayanan 1999; Pisani et al. 1999). For example, where cytology-based (Pap smear) testing has become commonly available, cervical lesions are detected at the precancerous stage, when treatment is effective and cancer can be averted. As a result, deaths from cervical cancer have been considerably reduced in a number of developed countries.

Despite the fact that 80% of cervical cancer cases are in developing countries, only approximately 5% of eligible women in developing countries actually undergo testing, usually cytology-based, in a 5-year period (World Health Organization 1986). The failure of the conventional cytology-based approach to reduce high rates of cervical cancer in developing countries is attributed to several factors. First, there are too few trained and skilled professionals to implement such a program effectively. Moreover, health care resources available to sustain the program are limited. In those countries where cytology based services exist—usually in exclusively urban areas—women's lack of awareness about, and limited access to, prevention services limit demand, thereby further contributing to low screening rates. Delays in reporting cytology test results, limitations in infrastructure, and low levels of literacy reduce the likelihood that test-positive women ever receive their results, making it even less likely that test-positive women receive treatment, or return for followup. These and other barriers may prevent women from ever seeking screening as well as providers from ever recommending the procedure (Fylan 1998).

Recent studies have demonstrated the potential of visual inspection using acetic acid (VIA) as an alternative test to Pap smears in the identification of cervical lesions (Abwao et al. 1998; Sankaranarayanan et al. 1999; University of Zimbabwe/JHPIEGO Cervical Cancer Project 1999). VIA testing is not only inexpensive and simple, it can also be provided at all levels of the health care system by nurses and midwives. A key advantage of VIA testing over cytology-based

services is that results are immediately available. This means that management decisions, especially whether to offer outpatient treatment if the cervix is found to be abnormal, can be made during a woman's initial visit (Kitchener and Symonds 1999; Parkin and Sankaranarayanan 1999).

One strategy for optimizing the preventive effects of testing in low-resource settings is to couple testing with an immediate offer of diagnosis and/or treatment for test-positive cases—essentially a "single visit" approach (SVA) (Holschneider et al. 1999). Given the evidence to date supporting VIA as a viable testing method, demonstrating whether VIA can be efficiently linked to safe treatment in low-resource settings was a logical next step to assess its potential role in cervical cancer prevention programs in developing countries. A VIA-based SVA differs from the traditional approach to cervical cancer prevention in that referral for diagnostic testing (e.g., colposcopy and biopsy) is limited *only* to cases that are not eligible for immediate treatment (e.g., due to lesion size).

GHANA

Cervical cancer is the most common cancer of women in sub-Saharan Africa. In West, East, Central, and Southern Africa, cervical cancer accounts for 20–25% of all new cancers among women (IARCPress 2002). Effective screening and treatment services are scarce or nonexistent and many women in countries with limited resources, such as Ghana, die from this highly preventable disease.

In the absence of a national cancer registry, the incidence of cervical cancer in Ghana must be estimated from other sources. The most recent data reported by IARC indicate that cervical cancer represents 15.0% of all new female cancers in less developed regions of the world (Ferlay J. et al. 2004). In the absence of a national cancer registry, hospital-based records are the primary source of local cervical cancer data. At Korle Bu Teaching Hospital, the chief of the Pathology Department reported in 2001 that cervical cancer represents 60.5% of the cancers of the female reproductive system seen at the hospital, 70% of which presented with advanced disease; in addition, cervical cancer represents 13.6% of all malignancies identified by this department (personal communication, Dr Kwame Wiredu, Department of Pathology, Korle Bu Teaching Hospital). Since the Korle Bu Radiotherapy & Nuclear Medicine Centre began operation in October of 1997, fully 27.8% (295/1,063) of all referred cancer cases were cervical cancer. Each day, approximately two new cases of invasive cervical cancer, or almost 500 cases per year, are seen at Korle Bu Radiotherapy Center. Of these, approximately 50% can be offered only palliative care—of limited scope and variable quality—due to the advanced stage of disease (personal communication, Dr Baffour Awuah, Radiation Therapy Center, Korle Bu Teaching Hospital). These numbers do not account for the unknown numbers of women who die at home, beyond the reach of the formal health care system.

Cervical cancer is clearly a reproductive health issue deserving attention in Ghana; however, no national cervical cancer prevention program exists. Cytology-based detection of precancer is available, but is offered only when specifically requested by women—generally, educated, urban women—who are obliged to purchase their own test kit, at a cost of approximately USD$ 7.00, an amount constituting 2.5% (USD$ 7/USD $270) of the average per capita income (World Bank Data and Statistics, Ghana Quick Facts 2002).

Without reliable national statistics on screening, current coverage rates are nearly impossible to estimate. Insofar as contraceptive prevalence is a marker of the demand for reproductive health services, it is informative to observe that in 2000, approximately 20 years after the initiation of family planning programs, Ghana had achieved a modest 22% contraceptive prevalence (World Bank, Summary Gender Profile 2002). Cervical cancer screening rates can reasonably be expected to be similarly low. A snapshot of screening rates at a busy urban gynecology clinic are illustrative: in 2000, the outpatient gynecology unit at Korle Bu Teaching Hospital in Accra, a city with approximately 300,000 eligible women, performed 1,500 Pap smear tests.

Processing of cytological slides is a complex activity, and is further complicated by weak infrastructure of personnel, supplies, equipment, and reporting mechanisms. There are few pathologists and cytotechnicians in Ghana; those who exist are found primarily at the teaching hospitals located within the two largest urban centers, Accra and Kumasi, or in the private sector.

In the event that the results of the Pap smear are abnormal, referral for advanced diagnosis, or treatment, is the next step. Unfortunately, there is no centralized referral clinic for dysplasia in Ghana. Furthermore, existing screening services, such as they are, are not coordinated with tertiary care services offered at the university teaching hospital, ultimately resulting in inadequate treatment planning for women with suspect, or histologically confirmed, cervical cancer.

Knowledge of cervical cancer and screening in Ghana is reportedly low, even among well-educated women (Adanu 2002); opportunities to learn much about reproductive health are beyond the reach of many women, particularly in rural areas. A diagnosis of cancer carries the same stigma in Ghana as in other countries around the world. In Ghana, where people customarily seek health care only when they are symptomatic, a program of preventive screening can be expected to require substantial investment in outreach and education, in order to ensure sufficient demand.

In 2001, the Ministry of Health (MOH) of Ghana, in collaboration with the Cervical Cancer Prevention Program (CECAP) of JHPIEGO, began a demonstration project designed to evaluate the safety, acceptability, feasibility, and program effort (SAFE) associated with implementing a VIA- and cryotherapy-based SVA to cervical cancer prevention in a low-resource setting (see **Table 1**). Other objectives of the project centered on local and national goals.

To realistically extrapolate study findings, this project was implemented in realistic settings. It was important to demonstrate the ability to train nurse-midwives to competently perform both VIA and cryotherapy under field conditions, and to have them confidently treat or refer women with suspect precancerous lesions or suspect cancer. To do this, field-based, competency-based learning materials were developed, and a group of providers, supervisors, and clinical coordinators were trained to implement and support project activities. Finally, ways in which large-scale VIA-based SVA programs could be implemented nationally had to be identified. This report describes key results of this demonstration project involving an alternative, field-based, resource-appropriate approach to cervical cancer prevention.

Women with abnormal VIA results who were ineligible for immediate treatment were initially referred to and managed by physicians at Ridge Hospital and, when appropriate, these physicians referred the women to Korle Bu Hospital.

In order to address the lack of coordination and treatment planning described above, JHPIEGO, GHS and staff of Korle Bu Teaching Hospital collaborated to form a functioning tumor board within the Obstetrics & Gynecology Department. This group, called the Multidisciplinary Cervical Cancer Care Group or "MC^3," comprised gynecologists, pathologists, and radiation therapists who convened regular meetings to review and manage the care and treatment of women with suspect cancer who were identified through the SAFE project. JHPIEGO subsidized the care and treatment of all women found to have biopsy-confirmed cervical cancer.

TABLE 1. SAFE PROJECT QUESTIONS

TOPIC	QUESTION(S)
Safety	• What were the rates of minor and major post-treatment complications? • Were women with large lesions or advanced disease appropriately referred?
Acceptability	• How many women in the clinic opted for testing when it was offered? • How many women who were test-positive agreed to treatment on the spot? How many were referred or refused treatment? • To what extent were women successfully able to carry out post-treatment home care as prescribed by the provider? • To what extent did the women's partners support the women in carrying out the prescribed home care, including abstinence or use of condoms for 4 weeks following treatment, and returning for followup visits? • To what extent were women satisfied with the decisions they had made regarding cervical cancer prevention? • To what extent are participating providers willing to continue to use a test-and-treat approach? • To what extent do these providers feel the benefits of this approach outweigh any risks? • To what extent are participating clinics willing to continue to use this approach?
Feasibility	• To what extent were providers able to test and treat target numbers of women during the project period? • To what extent were supervisors able to carry out their tasks as outlined in the protocol? • To what extent could project staff make the project quality assurance system operational? • What effect did offering VIA-based testing and immediate treatment for 6 months, coupled with patient followup for 12 months, have on routine service delivery?
Program Effort	• What was the 12-month test-negative rate (absence of acetowhite lesions) among women choosing to have treatment?

METHODOLOGY

TIME FRAME

The project was designed to provide testing and treatment for women during an 18-month period; women receiving treatment were followed for an additional 12 months.

SITE SELECTION

The urban phase of this project was conducted at Ridge Hospital, a regional hospital located in the Accra Metropolitan District of the Greater Accra Region in Ghana. The project was initially confined to this single site, due to human and resource limitations, despite the risk that results might be less reliably generalized for all of Ghana. Ridge Hospital was selected for several reasons: first, its working family planning clinic with a high utilization rate; second, availability of on site Ob/Gyn physicians for the purposes of supervision and clinical backup; and third, its proximity to the Korle Bu Teaching Hospital, to which biopsy-confirmed cervical cancer cases were referred, and where the Multidisciplinary Cervical Cancer Committee (MC^3) was housed. Korle Bu Teaching Hospital is located in Accra, approximately 5 miles from the project site, and is easily accessible by public transportation.

PROVIDER SELECTION

The hospital authorities identified four providers who met provider eligibility criteria (see **Provider Eligibility Criteria** text box). All of these providers were nurse-midwives on staff at the family planning clinic of Ridge Hospital. Already experienced in counseling and health promotion skills, these providers enjoyed more accommodating schedules and facilities, which increased the likelihood of adherence to clinical, counseling, infection prevention and related standards.

Provider Eligibility Criteria

- Nonphysician: registered nurse, midwife, or other types of health care provider
- Experience performing pelvic examinations
- Adequate eyesight (natural or lens-corrected)*
- Willing to attend and be assessed as competent during a training course involving VIA and treatment for cervical lesions
- Able to make a treatment decision and competently and confidently perform the treatment procedure immediately (if appropriate) following testing

**Assess eyesight through the use of a visual acuity chart and inspection for cataracts.*

Before launching the project, a Memorandum of Understanding was established by the Ghana MOH and JHPIEGO/CECAP. Institutional review and approval was secured from the Western Institutional Review Board (WIRB), USA, and the Committee on Human Research Publication & Ethics of the University of Science & Technology, Ghana.

Clinical supervisors were trained in January 2001. The clinical supervisors were five experienced Ob/Gyn consultants on staff in the Ob/Gyn departments at Ridge Hospital and Korle Bu Teaching Hospital. These supervisors completed a competency-based training course

in VIA, cryotherapy, punch biopsy and supervisory skills; training was followed by a 2-month practicum period.

Upon completion of the supervisors' practicum, a team of service providers was trained in a 2-week competency-based course in March 2001. The clinical supervisors served as co-trainers. The service providers participating in the training course were experienced nurse-midwives, as described in the **Provider Eligibility Criteria** text box. The course consisted of training in VIA, cryotherapy, and counseling for cervical cancer screening in classroom and clinical settings. During training, trainees participated in sufficient clinical practice to be assessed as competent according to guidelines agreed upon by the participating institutions. Classroom practice with anatomic models and digital media, such as CD-ROMS, helped participants to achieve competency with VIA and cryotherapy. Using anatomic models has been shown to reduce the time required to achieve competency during clinical practice (Limpaphayom et al. 1997).

A 1-month pilot phase, during which service providers' proficiency in VIA, cryotherapy, and counseling was assessed, followed the competency-based course. During the pilot phase, clinical supervisors conducted an intensive schedule of supervisory visits. The evaluations featured a co-assessment of the service providers' VIA and clinical decision-making skills.

STUDY PARTICIPANTS

The objective of the 18-month enrollment period was to enroll and provide VIA testing to approximately 3,000 women. The proposed target group was 25–45 years of age. The upper age limit reflects the fact that recent studies on VIA test qualities in developing countries have typically included women under age 50. This upper limit also reflects that the transformation zone in menopausal women is less visible, making visual inspection more difficult and potentially less accurate. Because the project focuses on identifying and treating precancerous lesions, the lower age limit was established as the peak age at which high-grade squamous intraepithelial lesion (cervical intraepithelial neoplasia [CIN] II and III) is thought to occur—approximately 10 years younger than the peak age of invasive cancer (Program for Appropriate Technology in Health 1998). Assuming the test-positive rate in the population would be a maximum of 20%[1], 600 women (of the 3,000 screened) would potentially qualify for, and be offered, immediate treatment.

Exclusion criteria for study participants disqualified those who:

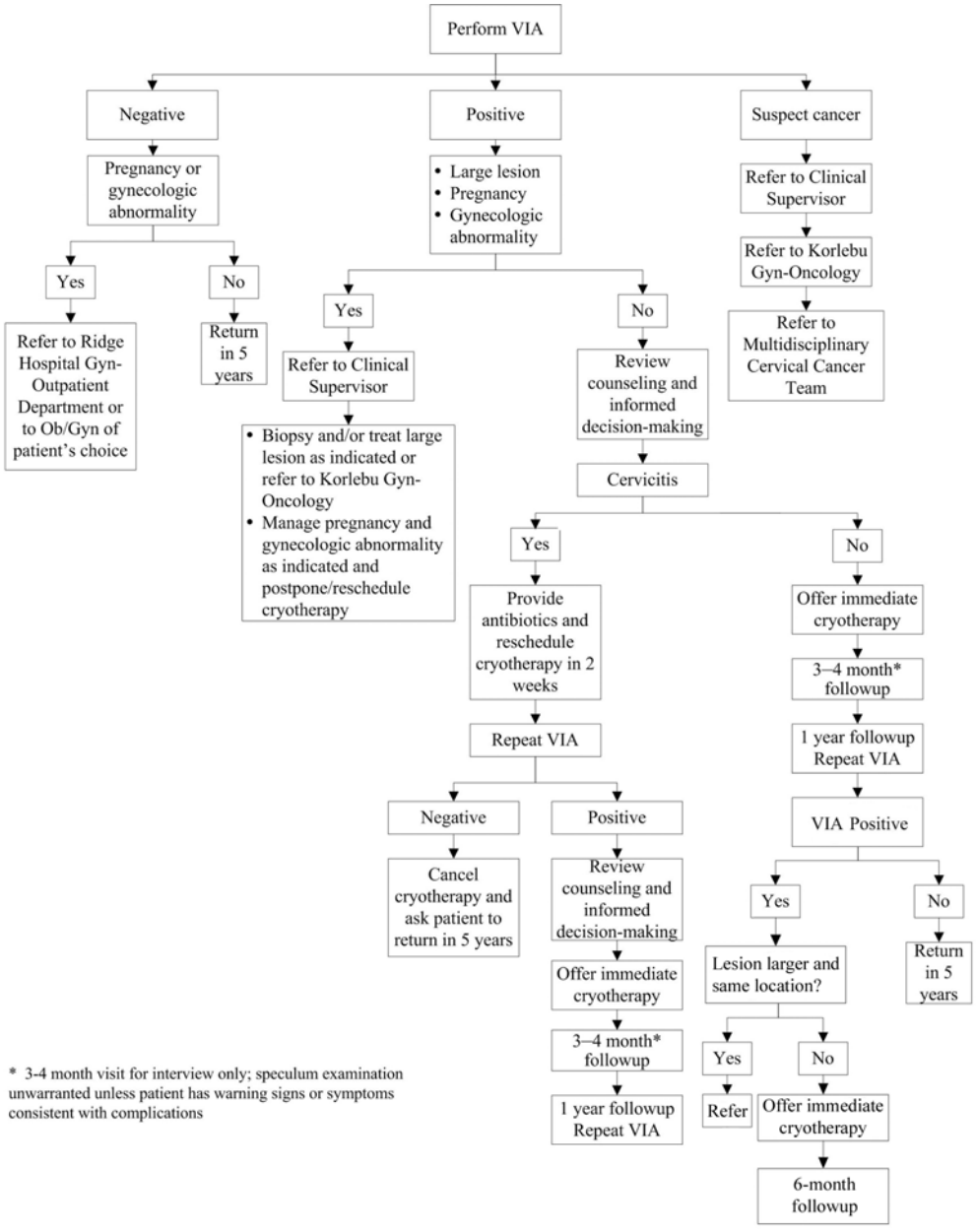
- Had a total hysterectomy (cervix and body of uterus removed) or their cervix removed
- Had previous known diagnosis of cervical cancer
- Were pregnant by clinical examination (because treatment can be delayed without disease progression until after childbirth)

[1] A test-positive rate of 10–20% has been observed in studies of populations with high prevalence of and minimal screening for cervical cancer (Ferlay 2004).

CLINICAL PROTOCOL

The generic clinical protocol for the SAFE Project was designed to fit into ongoing testing and treatment activities in each country. **Figure 1** outlines how the generic protocol was adapted to suit the Ghana context.

FIGURE 1. SAMPLE FLOW DIAGRAM FOR CERVICAL CANCER PREVENTION



VIA testing was offered at Ridge Hospital's family planning clinic. Test-positive clients were assessed for treatment eligibility. Treatment-eligible clients were offered immediate cryotherapy; treatment could also be postponed to a later date. Treatment ineligible clients were referred to clinical supervisors, who could repeat VIA and perform cryotherapy. Women with large lesions or suspect cancer were considered ineligible for treatment and were biopsied and asked to return in 2 weeks. Histopathological specimens were analyzed at the Pathology Department of Korle Bu Teaching Hospital, and results were generally made available within 2 weeks. Women returned

to Ridge Hospital to receive counseling regarding their results and options for further treatment, if any. If invasive cervical cancer was confirmed, then the clinical supervisor at Ridge referred the woman to the MC[3] for such care. The Clinical Supervisors referred only women with biopsy-confirmed invasive cervical cancer to the tertiary care referral site.

For the purposes of this project, the clinical protocol involved a minimum of three visits:

- An initial intake visit included testing and, if appropriate, treatment
- If the woman received treatment, an initial followup visit scheduled at 12–16 weeks
- A final followup visit scheduled at 12 months (to assess the persistence or absence of acetowhite lesions)

RECRUITMENT

Women of eligible age attending Ridge Hospital's family planning clinic for any reason during the 18-month recruitment period were invited to participate. In addition, by means of informal outreach the providers actively recruited women at, for example, their own religious, business, or social gatherings.

Sample Size

One of the key questions regarding the use of cryotherapy in low-resource settings is the safety of the procedure when provided by non-physicians. Clinical experience with cryotherapy in developed countries has been associated with a complication rate of less than 5%, which we anticipated would also be the case in this project. To ensure that we could detect a rate this low (i.e., 4%) with adequate (± .02) precision, the number of women who needed to be treated during the project period was determined as follows[2]:

N = 1.96^2*.04*.96/.02^2 = 368.79 or 370 women treated with cryotherapy[3]

Given a likely minimum test-positive rate of 10%, a minimum sample size of 3,700 women was recommended in order to reach a treatment sample size of 370.

Health Education

All women presenting to the testing site attended a group education session led by the trained service providers. During this session the providers discussed the following key points:

- Cervical cancer as a disease and consequence of a sexually transmitted infection (STI)
- Risk factors for disease
- Role and importance of VIA testing
- Consequence of not being tested
- Treatment options if the VIA test is abnormal
- Expected side effects of treatment
- Possible treatment complications (minor and major)

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[2] Assume a binomial distribution for estimating the confidence interval around a proportion and that project women represent part of an infinitely large population.

[3] p= estimated proportion = 0.04; q=1- p = 0.96; d= margin of error = .02; Z = value of alpha at .05 = 1.96; and N= required sample size = 370.

INITIAL INTAKE

After group education, providers conducted a one-on-one initial intake interview with each interested woman. During the course of this interview, service providers determined the woman's eligibility, obtained signed informed consent, and recorded a brief reproductive health history for each eligible woman. Service providers also asked the women questions about exposure to various risk factors. The risk factors addressed can be seen in **Figure 2**.

FIGURE 2. RISK FACTORS FOR CERVICAL CANCER

- Sexual activity (initiated before age of 20 years)
- Multiple sexual partners
- Exposure to STI
- Mother or sister with cervical cancer
- Previous abnormal Pap smear
- Smoking
- Immunosuppression
- HIV/AIDS
- Chronic corticosteroid use (for asthma and lupus)

VIA TESTING

Following the initial intake interview and counseling, the nurse provider prepared the woman for physical examination and testing. The provider positioned the woman on the examination table, inserted the speculum, locked it in place and visualized the cervix. A dilute (3–5%) solution of acetic acid was then applied and, after 1 minute, the provider examined the entire cervix using a hand-held flashlight or "torch." Special attention was paid to observing the entire squamocolumnar junction. Nurse providers referred to JHPIEGO's VIA cervical atlas, which was used during training, to make the VIA assessment. The assessment findings were recorded using the standardized categories on the VIA form along with other relevant information, such as drawings, or "cervical maps" (see **Table 2**).

TABLE 2. VIA CLASSIFICATION RELATIVE TO CLINICAL FINDINGS

VIA CLASSIFICATION	CLINICAL FINDINGS
Test-Positive	Raised and thickened white plaques
Test-Negative	Smooth, pink, uniform, and featureless; ectropion, polyp, cervicitis, inflammation, nabothian cysts
Cancer	Cauliflower-like growth or ulcer; fungating mass

TREATMENT: CRYOTHERAPY AND REFERRAL

Test-positive women meeting the following criteria were considered eligible for immediate treatment:

- lesion was not cancerous,
- lesion did not extend onto the vaginal wall,
- lesion occupied less than 75% of the cervix,
- lesion extended less than 2 mm beyond the diameter of the cryotherapy probe,
- no cervicitis,
- no polyps present,

- no evidence of pelvic inflammatory disease, or
- not pregnant.

If the woman met the eligibility criteria, the providers reviewed with her, in more detail, the options for management and treatment. The providers explained what was involved with the treatment procedure—the benefits, risks, potential side effects, and their management—as well as the advantages and disadvantages of immediate treatment (see **Table 3**). The woman then made an informed choice regarding treatment.

TABLE 3. EXPECTED SIDE EFFECTS OF CRYOTHERAPY

SIDE EFFECT	MANAGEMENT
Cramping	• Counsel patient before the procedure that she should expect some degree of cramping **during** and **after** the procedure, and that cramping usually stops shortly after the procedure. • Reduce cramping by pressing lightly on the cervix with the cryotherapy probe. • If cramping is severe, provide oral analgesic (acetaminophen or ibuprofen).
Vaginal Discharge (Profuse, Watery)	• Counsel patient to expect a discharge lasting 4–6 weeks. • Counsel patient to expect discharge color to change from a pink tint to clear white or a yellow tint (occasionally streaked with blood). • Counsel patient to return if discharge changes to foul-smelling or is pus-colored (if so, evaluate for infection and treat with antibiotics). • Strongly advise abstinence for 4 weeks. • If abstinence is unlikely, advise condom use for 4 weeks to prevent pelvic infection.
Spotting/Light Bleeding	• Counsel patient to expect spotting/light bleeding for 1–2 weeks. • Counsel patient to return for evaluation if there is heavy bleeding.

Women assessed as test-positive who had evidence of purulent cervicitis[4] were not offered immediate cryotherapy. Women with purulent cervicitis were managed according to the Ghana Reproductive Health Protocols for cervicitis. This included treatment with Tetracycline (500 mg qid 7), Ciprofloxacin (500 mg stat) and Metronidazol (400 mg tid x7). These women were offered repeat VIA testing and cryotherapy treatment 2 weeks after completing the antibiotic treatment. If found to be VIA test-positive upon repeat testing, the woman was offered immediate cryotherapy; if found VIA test-negative, the woman was counseled to return in 5 years.

Providing antibiotic treatment to women suspected of having purulent cervicitis could potentially reduce the very small risk (less than 1%) of pelvic infection following cryotherapy.

[4] Purulent cervicitis is defined as yellowish mucopus in the cervical os or canal, a cervix that is beefy red and bleeds easily when touched, or a urethral discharge.

For women choosing immediate treatment, providers described in greater detail what to expect during the treatment as well as the steps involved in the procedure. The woman was then provided with a place to sit comfortably until cryotherapy could be performed. Waiting time for treatment was not to be longer than 1–2 hours. If a longer wait was unavoidable, the woman was given options to either return the following day or another day, or to remain and wait for treatment.

Cryotherapy was provided according to the treatment protocol. A standard probe was applied and the double freeze technique used as outlined in Chapter 6 of JHPIEGO's VIA training manual (McIntosh and Blumenthal 2001). Following treatment, the woman was allowed to rest in a private area before leaving the health facility. Oral analgesics (acetaminophen or ibuprofen) were given if the patient had severe cramping following treatment.

Table 4 lists what actions were to be taken for women who were either not eligible for, or chose something other than, immediate treatment. All referral decisions were documented on the VIA form.

TABLE 4. RECOMMENDED REFERRAL ACTIONS

STATUS	REFERRAL ACTION
Women suspected of having cervical cancer	Provider refers immediately to on-site clinical supervisor for further assessment. Supervisor may refer to MC[3] for advanced treatment.
Test-positive women whose lesions occupy greater than 75% of the cervix or extend more than 2 mm beyond the outer edge of the standard cryotherapy probe	Provider refers to on-site clinical supervisors for biopsy. If the woman is deemed unlikely to return for the referral visit, counsel about the greater likelihood of persistence of the lesion at 12 months and the need for having treatment again.
Test-positive women who fulfill criteria for immediate treatment but who request to be treated using a procedure other than cryotherapy	Provider counsels about the advantages and disadvantages of all treatment methods. Refer to closest facility offering treatment of the woman's choice.
Test-positive women who request further (more diagnostic) testing, not offered at the site	Provider refers to on-site clinical supervisor, who may then refer woman elsewhere (as indicated).
Test-positive women declining any treatment	Provider counsels about the likelihood of disease progression and prognosis. Recommend a return visit within a year for a repeat VIA test to reassess disease status.

COUNSELING FOLLOWING CRYOTHERAPY

Before leaving the health facility, women received counseling regarding:

- The details of self-care at home,
- When they should return for their next visit, and
- Conditions under which they should come to the clinic for care outside of the scheduled visits.

Women were instructed to come in as soon as possible and not wait if they experienced symptoms of any complications/warning signs (see **Warning Signs** text box, below).

Warning Signs

If you have any of the following, you should return to this or the nearest health facility:

- Fever for more than 2 days
- Severe lower abdominal pain, especially if you have a fever
- Bleeding heavier than your heaviest days of menstrual bleeding for more than 2 days
- Bleeding with clots

Women were counseled to abstain from sexual relations for 4 weeks following treatment and were given a supply of condoms to reduce the risk of pelvic infection. Women were also provided with a daily diary in which to record the time of onset of any side effects or symptoms of complications, sexual activity, use of condoms, and any other information related to the recommended home care. These women were instructed to bring the diary back with them every visit (scheduled or not) and they were given a visit schedule card as a reminder of when to come back for their followup visit.

FOLLOWUP VISITS

First Followup Visit

The first followup visit was scheduled sometime between 12 and 16 weeks following treatment. During the visit, the woman's post-treatment experience (e.g., when watery discharge ceased) was reviewed and any concerns or problems she had since being treated were addressed. The visit also included a question and answer period to assess how well the woman had been adhering to home care instructions. If a woman complained of lower abdominal pain or persistent vaginal discharge, a pelvic examination was considered necessary to check for potential vaginal, cervical, or pelvic infection.

The diary provided to women during their treatment visit was reviewed. All data collected during this 12 to 16 week visit were recorded on the first post cryotherapy followup visit form. During the first followup visit, women were asked questions about their own and their partners' attitudes toward the test-and-treat experience. Women were reminded of the date of their 12-month visit and the importance of returning when scheduled to have the condition of their cervix assessed by a trained provider. Their visit schedule card was used to remind them of the date of this visit.

Unscheduled Problem Visit

Any unscheduled visit was defined as a problem visit if it occurred outside of the time ranges established for scheduled visits. A special form was used for recording data pertaining to any problem visit.

One-Year Followup Visit

The 1-year followup visit was scheduled for 12 months following treatment and involved a pelvic examination. Because the SCJ (and the transformation zone) could have been visible, a speculum examination was performed, during which VIA was performed and the cervix carefully checked to assess how it had healed and whether any lesion persisted. All who were found test-negative at 1 year were counseled to return for repeat testing in 5 years. All women who were test-positive at 1 year and whose lesion was in the same location, as documented on the first cervix map, were offered immediate cryotherapy. These women were counseled to return for followup 6 months later. Women whose lesion was in a different location, or whose lesion was greater than 75% of the cervix area, were referred to the on-site clinical supervisors. The on-site clinical supervisors would perform punch or cone biopsy as indicated, or refer the woman to the MC^3 group for advanced diagnosis and management. Women were counseled during the 1-year visit about what additional care might be needed, depending on their treatment status. In addition to the clinical examination, their responses to questions about their attitude and those of their partners about their treatment experience were recorded on the designated form.

Post-treatment followup rates were initially low. Two different strategies were undertaken in order to address this problem: client tracing and mass media. Initially, one public health nurse was recruited to actively track lost-to-followup women (women who had missed their first scheduled followup visit). By visiting the woman's home or workplace, the followup nurse was able to successfully trace some women. The followup nurse was trained to conduct the first followup interview on the spot. In the event that the lost-to-followup woman required a 1-year followup visit (a visit which requires a VIA test), the followup nurse tried to motivate the woman to return to Ridge Hospital's family planning clinic.

The second strategy employed to encourage followup visits, a radio-based campaign, was designed to motivate women who had missed their scheduled 1-year followup visit. This radio campaign, created in partnership with a local Ghanaian health education agency, used a brief advertisement to inform and motivate those women to return to Ridge Hospital's family planning clinic for their schedule 1-year visit.

SUPERVISION

A critical component of the project was the transfer of learning to, and routine clinical supervision of, the providers by clinical supervisors. Supervision involved an assessment of how the quality assurance and referral systems were working. As noted earlier, before assuming the role of supervisor, the three Ob/Gyns from Ridge Hospital's Ob/Gyn Department and the two Ob/Gyns from Korle Bu Teaching Hospital's Ob/Gyn Department were trained and qualified as experts in both VIA testing and cryotherapy.

Intensive supervision was performed during the early phase of the project, and ratcheted downwards once providers had been assessed as competent in VIA and cryotherapy skills. The purpose of the intensive supervision was two-fold—first, to ensure adequate implementation of the SAFE Project protocol, and second, to reassess the competency of the service providers following completion of their training and the start-up of services.

During the first 2 weeks of the project, supervisory visits were conducted daily. As the confidence of the providers increased and as the level of agreement remained high (above 80%) the frequency of supervisory visits was reduced to once per week. Weekly supervisory visits were made during the first 6 months of the project. Beyond 6 months, visits were made as deemed appropriate by team members and/or as determined through the monitoring of selected quality assurance indicator values (see **Table 5**).

TABLE 5. PROJECT QUALITY ASSURANCE INDICATORS

AREA	INDICATOR	HOW TO CALCULATE
Overall Services	Recruitment rates	• Number of women recruited for VIA during last month/Total number of women eligible for VIA testing
	Initial and final followup visit rate	During a period of time: • Number of women coming for repeat VIA testing/Number of women getting first VIA testing • Number of women coming for followup after cryotherapy/Number of women who received cryotherapy treatment
Counseling	Proportion of providers providing counseling to standards	• Number of providers performing VIA and cryotherapy counseling to standards/Total number of providers providing VIA and cryotherapy counseling
	Proportion of women adhering to home care requirements	• Number of women adhering to home care requirements/Total number of women advised on home care requirements
VIA Testing	Test-positive rates	• Number of women testing positive to VIA/Number of women getting VIA test
	Proportion of providers able to delineate the extent of the acetowhite lesions*	• Number of providers able to delineate the extent of acetowhite lesions/Number of providers performing VIA at the site
Clinical Decision-Making	Proportion of providers making appropriate case management recommendations*	• Number of providers making correct case management recommendations/Total number of providers providing VIA services
Cryotherapy	Cryotherapy rate	• Number of women getting cryotherapy/Number of women getting VIA tests
	Complication (minor and major) rate	• Number of women experiencing complications following cryotherapy/Number of women getting cryotherapy

* Required "co-assessment" of cervix with trainer/supervisor

Supervisors assessed the VIA test skills of providers by direct observation using the appropriate checklist, and the disease recognition capabilities of providers using the standardized cervix slide set or computer-generated images. Supervisors also assessed the appropriateness of treatment decisions made by providers by referring to the standardized treatment criteria set up for this project. During all visits, supervisors followed the supervisory protocols and recorded their findings on a designated supervisory form.

Providers' skills in performing cryotherapy and their overall performance were also assessed during this visit by review of the providers' client records and by direct observation using the checklist. In addition, the supervisors used a special form on which to record findings of an independent VIA co-assessment examination (whereby the provider and supervisor independently assessed the same woman using VIA and recorded their results on separate forms before discussing their findings).

RESULTS

The following sections describe in detail the results from analyzing the data from forms that were administered throughout the study. These forms included the initial intake form, the VIA and cryotherapy forms, first followup visit form, problem visit form, and the final (1-year) followup visit form. On occasion, answers were not provided for every question on the form; in other instances, some forms were unavailable. For these questions, the number of omitted answers was subtracted from that variable's effective sample size, for reporting valid percentages. For this reason, sample sizes for the question responses vary throughout this report.

INITIAL INTAKE

This section describes the results from the initial visit questionnaire, which was filled out by a trained nurse during the woman's first visit to the health care facility. The form consisted of questions about general demographic and personal information, followed by inquires about the woman's medical and reproductive history.

Demographics and Personal Information

Age

The project targeted women aged 25–45 years. Each participant's age was verified, to the extent possible, by her date of birth to validate her eligibility for the study. Some women had inconsistencies between their stated ages and the ages calculated for them from the date of birth they provided. Given these discrepancies, the age range for analysis was expanded to include women greater than 20 years old or less than 50 years old. Using this expanded age range, only 1 woman was excluded from the analysis. Calculating the women's ages based on their actual birth date yielded a range from 22 years to 48 years old for the 3,657/3,665 (99.8%) women who provided this information. In terms of their age as reported in years, 3,653/3,665 women (99.7%) responded, and the range was from 25 to 45 years old.

Of the 3,653 women who reported their age in years, all ages from 25 to 45 were represented. The mean, median and mode for age were 33.9, 34.0, and 25, respectively. Over half (1,968/3,653 or 53.9%) were 34 years old or younger.

Access

Travel times to the facility varied from 1 to 2,400 minutes; however, for the majority of the women (83.9% or 3,023/3,604), travel time to the facility was within 60 minutes. Many women (42.4% or 1,528/3,604) took 30 minutes or less to reach the facility, and approximately 1/10th of the women (10.8% or 388/3,604) took 15 minutes or less.

Reasons for Attending the Health Facility

Of those who answered the question, "What was the main reason why you came to the clinic?" the majority responded that the reason for their visit was to get screened for cervical cancer. Additional reasons for visiting the facility (<2.1% or 76/3,641) included: sick child visits, the

woman's own health problem, antenatal care visits, family planning visits, accompanying another individual to the facility, or other miscellaneous reasons.

The women were asked who had originally suggested VIA testing to them. Staff at the facility where the initial visit took place, or staff at another health facility, were the source of this suggestion for 18.7% (648/3,467) of the women. Community health workers suggested VIA testing in 0.3% (10/3,467) of the cases. A large percentage of women, 36.2% (1,255/3,467), stated they came after talking to other women who had already been tested as part of the project. The radio, a ladies club, churches, and organizations were collectively the source of information for 6.6% (229/3,467) of the participants, and 31.4% (1,088/3,467) of the women sought a VIA test because a family member, friend, or neighbor had suggested that they attend the clinic. In addition, 2.2% (76/3,467) of the women indicated that some "other" source had prompted them to get tested.

Schooling

Of the women who had an initial intake evaluation form filled out, 306 (8.3% of 3,665) did not provide the number of years of schooling they had completed. Of those who responded, 2.7% (91/3,359) of the women indicated they had received no schooling, 2.1% (71/3,359) had completed 1–3 years of education, 9.5% (318/3,359) had finished at least 4, 5, or 6 years, and 44.1% (1,483/3,359) had completed 7–12 years of schooling. The remaining 41.6% (1,396/3,359) of women had attended school for more than 12 years, ranging from 13–27 years of total schooling. Nearly half (47.3% or 1,589/3,359) claimed that they had completed up to and including at least 11 years of schooling.

Reproductive and Medical History

The women were asked many questions about their gynecological, sexual, and medical histories. The information gathered was used to determine a woman's eligibility for treatment and to identify any risk factors for cervical cancer she may have had.

Gynecological History

The women were asked whether or not they used any vaginal herbal preparations. Of the 3,629 women who replied, 830 (22.9%) responded "yes" and 2,799 (77.1%) responded "no."

To further ensure that women were eligible to receive testing as part of the project, all were asked if they had ever had a hysterectomy. Three participants (0.1% of 3,665) responded that they did not know, and 87 women (2.4% of 3,665) failed to respond to this question. No one reported having a hysterectomy; thus, 3,575/3,665 (97.5%) women responded they had not had a hysterectomy. Furthermore, the women were asked if they had ever been diagnosed with or treated for cervical cancer. The vast majority (97.1% or 3,558/3,665) indicated they had not. Four women (0.1% of 3,665) responded that they did not know about such a diagnosis or treatment, and 103 women (2.8% of 3,665) had no response recorded for this question. No one reported ever having been diagnosed with or treated for cervical cancer.

Menstrual History

The date of each participant's last menstrual period was recorded. The majority of women (3,608/3,665 or 98.4%) indicated that they were not currently menstruating. Among the rest, 0.6% (22/3,665) provided a date that indicated that they had started menstruating 2 days prior, 0.7% (25/3,665) indicated that they were currently menstruating, and 0.3% (10/3,665) indicated the start of their menses was the previous day. In addition, each woman was asked whether or not she knew or suspected that she was currently pregnant. There was no response to this question from 163 women (4.4% of 3,665), and 4 women (0.1% of 3,665) responded "yes" to this question, or they gave a number of weeks that they believed they were pregnant (2/3,665 or 0.1%). Eighty-five women (2.3% of 3,665) responded that they didn't know, and the remaining 3,411 women (93.1%) believed they were not pregnant. The women who indicated they were pregnant or suspected they were pregnant were then asked how many weeks into their pregnancies they believed they were. Six women responded to this question, and they knew, or suspected, they were anywhere from 4 to 16 weeks pregnant. According to the clinical protocol, any woman determined by clinical exam to be pregnant was not eligible for SVA services.

Gravidity

In addition, all women were asked if they had ever been pregnant. A small number of women (48/3,665) failed to respond to this question. The majority (85.4% or 3,132/3,665) specified that they had been pregnant. Among these women, the number of pregnancies ranged from 1–14 (answered by 3,072 women), and the majority (21.0% or 646/3,072) had had two pregnancies. One pregnancy was recorded for 19.6% (602/3,072) of the women, 19.4% (595/3,072) of the women had been pregnant three times, 15.3% (471/3,072) of the women had been pregnant four times, and 10.4% (320/3,072) had been pregnant five times. The remaining respondents (14.3% or 438/3,072) indicated they had had six or more previous pregnancies. The mean, median, and mode for the number of pregnancies among those who had ever been pregnant were 3.3, 3.0, and 2, respectively.

Contraception

To gain a better understanding of the ways in which the women attempted to prevent pregnancies, questions asked the women to recall any and all forms of contraception that they had ever used with their husbands/partners. Only 13.5% (480/3,549) of the women indicated use of condoms and 0.9% (33/3,549) had received a tubal ligation as a means of preventing pregnancy. A small percentage of women (2.7% or 96/3,549) indicated that they did not engage in sexual intercourse during the safe period (natural family planning or the rhythm method), and a large percentage of women, specifically 60.3% (2,141/3,549), indicated that they did not use any form of contraception. Oral contraceptives were utilized by 9.7% (343/3,549) of the women, 6.8% (242/3,549) used DMPA (depot-medroxyprogesterone acetate), 0.8% (30/3,549) had received Norplant® implants, and 10.5% (371/3,549) had had an IUD (intrauterine device). Only 1 woman out of 3,549 (0.0%) indicated that her partner had undergone a vasectomy, and 37/3,549 or 1.0% used the withdrawal method of contraception (coitus interruptus). Seven women (0.2% of 3,549) indicated some "other" form of contraception, unspecified or specified, such as a diaphragm, and 2.4% of the women (86/3,459) indicated the use of spermicide. Overall, modern methods of family planning (oral contraceptives, DMPA, Norplant implants, tubal ligation, IUDs, condoms, diaphragms, and spermicides) were utilized now or in the past by 37.9% (1,345/3,459) of the women.

Spotting/Bleeding

The women were asked, "Within the last year, have you ever had bleeding or spotting after sex?" Such post-coital bleeding was recorded by 2.9% (105/3,564) of the women.

Risk Factors for Cervical Cancer

Risk factors for cervical cancer include smoking, a first degree relative with cervical cancer, a previously abnormal Pap smear, early sexual activity (e.g., <20 years of age), multiple sexual partners, exposure to a STI, and the presence of an immunosuppressive disease such as HIV/AIDS or immunosuppression via chronic corticosteroid use (McIntosh and Blumenthal 2001).

Sexual History

Over half of the women (58.7% or 2,097/3,573) had engaged in consensual or non-consensual sexual intercourse before the age of 20, and over three-fourths of the women (75.4% or 2,694/3,573) had done so by the age of 20. The age of their first sexual encounter ranged from age 5–35, the majority (97.3% or 3,475/3,573) reporting between the ages of 15 and 30. The mean age at first sex was 19.3, the median age was 19.0, and the modal age was 18. Many women (59.6% or 2,160/3,624) claimed to have had intercourse with someone other than their current or latest partner.

Partner History

When asked if their husbands/partners had engaged in sexual intercourse with anyone else, 60.0% (2,169/3,613) indicated that they had, 15.4% (556/3,613) indicated that they had not, and 24.6% (888/3,613) of those who responded did not know the answer to this query.

Previous Cervical Cancer Screening

Few women (2.8% or 99/3,513) had ever had a previous Pap test; 0.9% (30/3513) did not know if they had or not. Among those women with a previous test, eight women never found out the result of their test and 10 others did not respond whether the test was positive or not. Among the women who did report their test result, 5.1% (5/81) stated their tests were positive. Four of these 5 women (80%) were found to be negative by the VIA test; 15.8% (12/76) of the women whose previous tests were negative were found to have positive VIA results.

Partner Involvement

When asked if before attending the facility they had discussed with their husbands getting tested and possibly treated for cervical cancer, 63.3% (2,279/3,598) women claimed that this discussion had occurred, while 36.7% (1,319/3,598) did not have such a discussion.

HIV/AIDS and Other STIs

Eleven women (0.3% of 3,665) indicated that they had been diagnosed with HIV/AIDS. One of the 11 did have a positive VIA test, although none received cryotherapy. Many women (28.6% or1,049/3,665) said they did not know if they had HIV/AIDS, and 1.4% (51/3,665) failed to respond to this question. Twenty-nine (0.8% of 3,665) women said they had husbands/partners who had been diagnosed with HIV/AIDS, and 34.5% (1,263/3,665) indicated that they did not know the HIV/AIDS status of their partners. Among the women whose partners had tested positive for HIV, 10.3% (3/29) had positive VIA results.

With respect to signs and symptoms of STIs, the women were asked if they had any problems currently or in the past. Of the 3,596 women who provided information on STI symptoms, 14.8% (533/3,596) indicated pelvic pain with vaginal discharge, 12.3% (442/3,596) reported abnormal offensive vaginal discharge, 4.2% (155/3,596) indicated a history of or present genital ulcers/sores, and 0.2% (8/3,596) claimed to have or have had genital warts. Overall, 27.3% (981/3,596) women reported one or more of these problems at some time in the past.

The women were asked about STI symptoms of their current spouse/partner. Of the women who responded, 4.2% (151/3,586) indicated their spouse/partner had experienced pain on urination, 1.0% (35/3,586) suggested their partner had had abnormal offensive genital discharge, 1.5% (52/3,586) claimed they had had genital ulcer/sores, and 0.1% (2/3,586) of the spouses/partners were believed to have had genital warts. Overall, 6.0% or 215/3,586 reported one or more of these partner problems at some time in the past.

The women were then asked about STI symptoms of their earlier spouses/partners. Pain on urination was reported for 1.0% (35/3,585) of the previous spouses/partners, 0.3% (9/3,585) were believed to have had abnormal offensive genital discharge, 0.3% (9/3,585) were also believed to have had genital ulcer/sores, and 0.1% (2/3,585) supposedly had had genital warts. Overall, 1.3% or 48/3,585 women reported one or more of these problems in a previous partner and 7.1% or 254/3,587 reported one or more of these problems in either current or previous partner(s).

Combining reports by the woman for either herself or any of her partners, 30.3% or 1,088/3,587 reported one or more of these problems. Among women who reported ever having a STI symptom themselves, 15.2% (149/981) had a positive VIA test; however, 12.6% (330/2,615) of women who reported no such problems also had a positive VIA tests or suspect cancer. Results are similar if we consider women who reported an STI-related problem in either themselves or their partners: 15.3% (166/1,088) of women with reported STI symptoms themselves or in their partners, and 12.5% (312/2,499) of women with no reported STI symptoms themselves or in their partners, had a positive VIA test.

VIA

After completing the initial intake form, providers counseled all interested eligible women about the upcoming examination. After the VIA test was performed, providers asked the women to share perspectives about their experience of the test by means of a brief post-VIA questionnaire on the VIA form. Providers recorded the women's observations and opinions about the VIA procedure; in addition, the provider noted on the form whether each woman had

been counseled on all key points. This section describes the frequency distribution results for each variable on the VIA form.

Procedure

During the examination, the health care providers were to visualize the squamocolumnar junction (SCJ) of the cervix, perform the VIA assessment, and record the descriptive characteristics of any lesions present. The SCJ was easily visualized for 96.0% (3,518/ 3,665) of the women who took part in the project. It was visualized with difficulty for only 2.6% (95/3,665). The SCJ cannot be visualized if it is inside the cervical canal, as was the case for the remaining 7 (0.2%) women. The nurses recorded that the SCJ was not visible in 1 woman (0.0 %) because she had cervicitis, and 7 women (0.2%) had unobservable SCJs due to "other" reasons, such as adhesions, cervical growth, fibroids, or suspect cancer. The woman with cervicitis had a negative VIA test, and among those whose SCJ could not be seen due to other reasons, 1 had cancer, 1 was recorded as having suspect cancer but ultimately received cryotherapy, 3 were VIA negative, and 2 were VIA-positive—1 of whom received cryotherapy.

Based on the project's defined VIA classification categories of those tested, 86.7% (3,178/3,665) women were test-negative and 13.2% (484/3,665) were classified as test-positive. The eligibility for treatment of test-positive women was subsequently evaluated. Cancer was suspected or overtly labeled for 3 women (0.1%).

DETERMINING ELIGIBILITY FOR IMMEDIATE TREATMENT

If a woman was assessed as test-positive, the health providers first drew the lesion on the cervix map and were guided through a specific set of questions on the form regarding the woman's eligibility for treatment.

For a woman classified as test-positive, if the acetowhite proportion of the total cervix exceeded 75% of the total surface area (estimated visually by using the cervix map), the protocol dictated that she would be ineligible for treatment. This was the case for 1 of the 475 women for whom these data were recorded (0.2%). If the acetowhite area extended beyond the cervix and onto the adjacent vaginal wall, the woman was also considered ineligible for treatment. According to the results for 475 women, none met this criterion for ineligibility and the remaining 474 women (99.8%) were eligible based on this criterion.

Other exclusion/ineligibility criteria included: a greater than 12-week fibroid mass, an ovarian/adnexal mass greater than 5 cm, polyps, pelvic inflammatory disease (PID), cervical anomalies/scarring, abnormal uterine bleeding, pregnancy, and current menstruation. Only 2 women (0.4%) of the 476 women for whom these data were recorded had a fibroid mass, 0.2% (1/476) had an ovarian/adnexal mass, 6 women (1.3% of 477) had polyps, 5 women (1.0% of 477) had cervical anomalies/scarring, 3 women (0.6% of 475) had abnormal uterine bleeding, and no woman (0.0% of 476) had evidence of PID. Thus, considering all the eligibility criteria, 468 test-positive women (97.5% of 480) were determined to be eligible for immediate treatment with cryotherapy.

Cases of Cervicitis

The test-positive women were evaluated for signs of cervicitis. Forty-four women (11.2% of 392) had signs of cervicitis at the time of VIA testing. Of the 44 women, data were recorded for 33, 36.4% (12/33) of whom were treated with oral antibiotics. It was recorded that one woman took the medication in the presence of the health care worker.

Clinical Management Plans, Referrals, and Consent for Treatment

A clinical management plan was devised for all test-positive women and women with suspect cancer. The three management options were: immediate treatment, postpone treatment, or referral. The provider indicated an initial recommendation, asked the woman what she wanted to do, and then recorded the final recommendation, based on the woman's decision. Overall management data were recorded for a total of 487 women. The providers recommended immediate cryotherapy treatment for the majority of test-positive, treatment-eligible women. Providers recommended treatment for 73.5% (358/487) of test-positive women for whom data were recorded.

Among those women whose providers recommended immediate treatment, the majority, 93.3% (319/342), gave consent for immediate treatment. Twenty-three women (12.3% of 464) did not give consent for immediate treatment. Of the 23 women who did not give consent for immediate treatment, 16 women (69.6%) claimed they needed to discuss the matter with their husbands/partners first, 1 woman (4.3%) claimed she did not have enough time that day, 1 woman (4.3%) needed to ask permission from her workplace, and 5 women (21.7%) provided no reason for not consenting. No women rejected the validity of their VIA test results. Of the 23 test-positives who did not give consent, 5 never received treatment, 12 were treated on a different day, and 6 did eventually accept immediate treatment.

Most test-positive women with treatment-eligible lesions accepted the offer of immediate treatment. More than 62% (328/488) received same-day treatment, 1.6% (8/488) were referred to clinical supervisors for treatment, 1.2% (6/488) were referred to clinical supervisors for further tests, 0.4% (2/488) were referred for another reason (e.g., "removal of polyp," "return in 2 weeks"), and 28.9% (141/488) were to return for cryotherapy on a future specified date (postponed). Three women out of 488 (.6%) had positive VIA test results, but no final recommendation was indicated.

Providers recommended postponement for a small number of women. Postponement was recommended for 23.2% (113/487) of test-positive women for whom data were available. Providers recorded their reasons for recommending postponement for 27 of these women. Postponement was recommended due to: the need for additional diagnostic tests (1), an ovarian/adnexal mass (1), cervicitis (5), polyps (1), candida (1), discharge (1), pregnancy (3), menses (2), and other non-specified reasons (3). Other reasons for postponement were: work-related (2), time constraint (1), and need to discuss things further with partner/husband (6). Reasons for referring women to other facilities were recorded for 15 women. Reasons for referral included: suspect cancer (5), an extensive lesion (1), the need for additional diagnostic tests (1), fibroids (1), polyps (3), cervical anomaly (3), or another non-specified reason (1).

Most women whose treatment was recommended for postponement (91.2% or 52/57 who had a response) were to be treated within 14 days, and 4 women had specific referrals (doctors' names

or a clinical supervisor) indicated. Providers attributed postponements to cervicitis (8.5% or 12/141, although not all VIA test-positive women with cervicitis were postponed), fibroids (0/141), ovarian/adnexal mass (0.7% or 1/141), current menstruation (1.4% or 2/141), malfunctioning or missing equipment (5.7% or 8/141), or other miscellaneous reasons (14.9% or 21/141). These latter miscellaneous reasons included the need to discuss treatment with the spouse/partner, time constraints, and pregnancy-related issues. Of those women for whom treatment postponement was recommended, 71.5% (98/137) were recorded as receiving treatment.

POST-VIA COUNSELING QUESTIONS

Providers counseled virtually all (99.9%) of the 3,665 women who participated in the project. Counseling addressed the following key points: the meaning of VIA results (99.9% or 3,586/3,591), the case management plan, including available treatment options (99.9% or 3,616/3,621), and when the woman should return to the clinic for additional cancer prevention services (99.9% or 3,620/3,622).

POST-VIA INTERVIEW: ATTITUDES TOWARD TESTING

Women's perspectives on the testing experience were assessed. Of the 3,617 women for whom data are recorded, the majority (85.1% or 3,079) said they experienced no discomfort, while 14.9% (538/3,611) indicated they experienced discomfort during the VIA procedure. Additionally, most (83.6% or 3,007/3,598) women asserted their testing experience was better than expected. For a small percentage (0.8% or 30/3,598) of women, the experience was worse than expected, 5.9% (213/3,598) had an experience that matched expectations, and 9.5% (343/3,598) had no expectation to begin with. Five women (0.1% of 3,598) failed to give a response to this question.

Women's perspectives on counseling were also assessed. Almost all (99.7% or 3,570/3,582) women believed that they were informed enough about what they would experience during the testing procedure, and 79.8% (2,889/3,621) were either very satisfied (57.4% or 2,000/3,621) or satisfied (22.3% or 809/3,621) with their decision to get VIA testing. Furthermore, based on the results of their test, 99.7% (3,602/3,612) were either very satisfied (82.0%) or satisfied (17.7%) with the management recommendation of the provider. Nearly all (99.2% or 3,566/3,593) women declared that they would, in the future, recommend the VIA test to female friends and/or family members. Only 1.6% of the 3,514 women for whom data exist had final questions or concerns that were expressed in writing on the back of their questionnaires.

CRYOTHERAPY RESULTS

A total of 439 women (12.0% of 3,665) received cryotherapy. Of those, cryotherapy forms were completed for 96.1% (422/439). For 17 others who received cryotherapy treatment, cryotherapy forms were incomplete or unavailable (3.8%). The following analysis describes results for the 422 women for whom information about their experiences with pre- and post-procedure counseling, general patient observations, and post-cryotherapy attitudes is available.

PRE-PROCEDURE COUNSELING

Each woman eligible for and interested in receiving cryotherapy was counseled about four key points: 1) their treatment options; 2) what the cryotherapy treatment itself entailed and what to expect during the procedure; 3) home care recommendations, such as the necessity for abstinence and the use of condoms for 4 weeks following the cryotherapy procedure; and 4) the need to return for two separate followup visits as part of the project protocol. The first followup visit was scheduled for 12–16 weeks after cryotherapy treatment, and the final followup visit was scheduled 1 year after cryotherapy.

Data for various questions were missing for some women. Overall, the data indicate that more than 98.3% of the women who received cryotherapy also received counseling on these four points.

CRYOTHERAPY PROVIDER OBSERVATIONS

Of the 422 women, 70.8% (299/422) received cryotherapy on the same day of their VIA testing. The procedure was postponed for the remaining 29.2% (123/422) of women.

Nurses perceived that 22.6% (93/412) of the women experienced pain or cramping during or immediately after the procedure. When asked to rate the perceived severity of the women's pain, of the 90 women for whom data are available, the nurses perceived 56.7% (51/90) to have experienced *very minimal* pain, and 28.9% (26/90) to have *minimal* pain. *Moderate* pain level was perceived for 12.2% (11/90) of the women, and the remaining 2 women (2.2% of 90) were perceived to have experienced either *severe* pain (1 woman) or *very severe* pain (1 woman). Of the 82 women for whom there were data, 8.5% (7/82) received an analgesic; 5 of those 7 (71.4%) received the analgesic after the procedure.

Of the 399 women for whom there were data, in 1.3% (5/399) bleeding occurred immediately after the cryotherapy probe was removed. The bleeding was assessed as *minimal* for 20.0% (1/5) of the women and *very minimal* for the remaining 4 women (80.0%).

There were no occurrences of *moderate* or *severe* bleeding immediately after the cryotherapy probe was removed. When asked how the bleeding was controlled, of the two responses given, nurses applied cervical pressure to control the bleeding for 1 woman, and used pads and reassurance for the other woman. None of the following were recorded as being utilized to control the bleeding: surface cervical medications, vaginal packing, sutures, admission, referral to the hospital, transfusion, or "other."

With the exception of bleeding, there was only one immediate adverse post-treatment event recorded for the 388 women who responded to this question. This event was recorded as a "slight headache." Further clinical action (e.g., a hysterectomy or an exploratory laparotomy) was not needed for any of the 439 women for whom there were informative data.

POST-CRYOTHERAPY COUNSELING

After treatment, nurses were instructed to counsel each woman about eight key points: 1) possible side effects that may occur secondary to treatment; 2) expected vaginal discharge; 3) post-treatment symptoms that may indicate a possible complication; 4) the importance of seeking medical attention if any of these symptoms occur; 5) how to obtain services at the district hospital if these symptoms develop; 6) the risk of putting anything in the vagina; 7) avoidance of sexual intercourse within the first 4 weeks post-treatment; and 8) the importance of using condoms if intercourse does occur within 4 weeks of treatment. Some data were missing for the eight questions; however, according to available data, 94.5% (418/439) of the women received counseling about all eight points.

POST-CRYOTHERAPY INTERVIEW

Attitudes toward Treatment

Women's perspectives on the cryotherapy treatment were assessed. The majority of women, 82.5% (353/428), said that their treatment experience was better than they had expected. Only 0.9% (4/428) of the women indicated that their experience was worse than they had expected. The experience matched the expectations of 4.4% (19/428) of the women, 7.2% (31/428) said that they had no expectations before the treatment, and 4.9% (21/428) gave no response to this question.

As a means of measuring immediate acceptability of the cryotherapy procedure, each woman was asked to first comment on the treatment, and then on how she felt about her experience. Less than one half of the women receiving treatment reported pain. Of the 413 women who responded, 34.9% (144/413) reported pain or cramping during the procedure. Of these women, 138 quantified their pain/cramping relative to their worst menstrual cramp. The majority of these women (85.8%) described their pain/cramping as either *very minimal* (55.8% women or 77/138) or *minimal* (29.7% women or 41/138). *Moderate* pain was reported by 13.8% (19/138) of the respondents, and 1 woman (0.7% of 138) said that she experienced *severe* pain.

For the women who responded about how adequately they had been counseled, the majority, 98.8% (407/412), felt that they were sufficiently informed about what to expect during the treatment. The remaining 1.2% (5/412) of women indicated that they were not sufficiently informed.

Partner Support

With respect to their husbands/partners, 2.9% (12/415) of the women believed that they would have problems convincing them to postpone intercourse for the recommended 4 weeks. This issue was not relevant for 11.5% (48/415) of the women who either did not have husbands/partners, or whose husbands/partners would be absent for the subsequent 4 weeks. The remaining 85.5% (355/415) of the women did not think at the time they received treatment that

they would have any problems convincing their husbands/partners to postpone intercourse for 4 weeks. Similarly, the majority of women—86.5% (359/415)—did not anticipate any problems convincing their husbands/partners to use condoms if they did have intercourse within the recommended abstinence period. Only 2.2% (9/415) of the women believed that this suggestion might be problematic.

Women's Perspectives

With the exception of 2 women (0.5% of 421) who were *unsatisfied* with their decision to have the condition of their cervix assessed with the VIA test, 98.1% (413/421) of the women were either *very satisfied* (72.4% or 305/421), *satisfied* (25.4% or 107/421), or *neutral* (0.2% or 1/421) about this decision. Regarding their treatment decision, 80.5% (339/421) of the women who responded were *very satisfied* with their decision to be treated for suspect cervical disease; 18.1% (76/421) were *satisfied*; and 1.4% (6/421) had no response to this question. Most women—99.8% (416/417)—indicated that they would recommend this treatment to their friends and/or female family members in the future. Only 0.2% (1/417) who received treatment claimed that they would not make this recommendation. After both counseling sessions and the cryotherapy procedure, only 3.9% (16/412) of the women had final questions or concerns, which were expressed on the back of their cryotherapy intake forms.

FIRST FOLLOWUP VISIT

Between 12 and 16 weeks post-treatment, women were instructed to return for their first followup visit. This section describes the results of their first followup visits. Of the 439 women who received cryotherapy, 76.8% (337/439) returned for the first followup visit. At this visit, the women responded to questions regarding compliance with home care recommendations, occurrence of any treatment side effects, their perspectives on their experiences thus far, and how much support they had received from their husbands/partners. Furthermore, if any woman had a major physical problem or complaint, the health care providers were to record the symptomatology and, if indicated, perform a clinical assessment.

PERSONAL QUESTIONNAIRE INFORMATION

Participants who completed their initial followup visit late, that is, after the 12–16 week post-treatment window had passed, were asked to provide a reason for the delay. In total, 47 women did not come back within the designated time period (calculated here as 10–16 weeks) and provided a reason for this. Of these, 6 women **(**12.8%) claimed they did not remember the date of their appointment, and 31 (66.0%) said that it was not convenient to come at the scheduled time. Ten women (21.3%) had "other" reasons for not attending, which included being involved in an accident (1), a sick child (1), a misplaced appointment card (1), and other travel (6). Three percent (10/330) of the women had moved or changed contact addresses after their cryotherapy treatment.

Women's Compliance with Home Care Recommendations

Each woman had been counseled about the risks associated with inserting anything into the vagina, having intercourse, and not using condoms should they have sexual intercourse within 4 weeks post-treatment. To document compliance and to inquire about other factors affecting the acceptability and safety of treatment, women were asked about compliance with the home care recommendations during the first followup visit. Many women (274/337 or 81.3%) brought completed daily diaries with them to their first followup visits to validate their post-treatment experience.

First Sexual Intercourse Post-Treatment

Of the 337 of the women who responded, 68.0% (229/337) had engaged in sexual intercourse during the 12–16 weeks post-treatment period. Of the 136 women who knew approximately how many days after treatment they had had sexual intercourse, 17.6% (24/136) said that they had done so within 4 weeks of their treatment. This indicates that the remaining 82.4% (112/136) of the women had abstained from intercourse for the recommended 4-week time period. By 40 days post-treatment, half—50.0% (68/136)—of the women had had intercourse. By 90 days post-treatment, the same was true of 96.3% (131/136) of the women. Data analyzed by week revealed the following: 1.7% (4/229) of the women who responded indicated that they had resumed intercourse within 1–2 weeks; 12.7% (29/229) resumed within 3–4 weeks; 14.4% (33/229) initiated intercourse during the recommended 4 week abstinence period; and 85.6% (196/229) had intercourse only after 4 weeks.

When asked why they had engaged in intercourse earlier than recommended, 23 women responded. Some of these respondents—21.7% (5/23)—said that they did not want to say no to or disappoint their husbands/partners. The remaining women had intercourse for six reasons: 14 women (60.9%) indicated that their husbands/partners forced them; 2 women (8.7%) claimed that their husband/partner(s) threatened to have intercourse with others if they were unwilling; 1 woman (4.3%) said that she was afraid of this latter possibility; and 1 woman answered "other" to this question.

Condom Use

Among the 33 women who report initiating sex during the first 4 weeks after treatment, 97.0% (32/33) did use condoms. All those who used condoms began using them on the same day they initiated intercourse. Among the condom users, 86.7% (26/30) used condoms all of the time during the 4 weeks, 10.0% (3/30) used them most of the time, and 3.3% (1/30) used them only some of the time. Only half (2/4) of the women who did not use condoms all of the time reported why they did not: 1 woman waited until after 4 weeks to stop using condoms all the time, and the other said her husband/partner refused to use them.

With respect to the use of condoms during intercourse, 62.0% (207/334) of the women claimed to have used condoms since their cryotherapy. Information regarding the date when condom use was initiated was recorded for 125 women via verbal estimates. Of the 125 women who estimated the number of days that had passed between their treatment and their use of condoms, 2.4% (3/125) said that they had used condoms within the first 14 days; 20.0% (25/125) had done so within 28 days; 69.6% (87/125) within 42 days; and 30.4% (31/125) sometime after 42 days. When asked to estimate by weekly increments when the use of condoms began, the data were slightly different, but the distribution was similar. Of the 332 respondents, 0.9% (3/332) used condoms within 1–2 weeks, 8.4% (28/332) within 3–4 weeks, and 52.4% (174/332) after 4 weeks post-cryotherapy. In addition, 32.5 %of the women (108/332) claimed they had not had sex, and the remaining 5.7% (19/332) claimed not to have used condoms. When asked how often they used condoms during intercourse, only 30 women responded (compared to the 207 women who originally claimed that they used condoms). Of these 30 women, 86.7% (26/30) claimed to have used condoms all of the time; 10.0% (3/30) said most of the time; and 3.3% (1/30) said some of the time. Only 2 women gave reasons why they did not use condoms all of the time: 1 woman claimed her husband/partner refused to use condoms, and the other woman thought that after 6 weeks it was safe to have intercourse without a condom.

Vaginal Insertion

Of the 334 women who attended their first followup visit, 18.3% (61/334) claimed to have inserted something into their vagina post-treatment. Of these 61 women, 30 (49.2%) were able to provide the number of days between their cryotherapy treatment and any vaginal insertion, which ranged from 8–150 days. Eight of these 30 women (26.7%) had inserted something into their vagina within 28 days of the cryotherapy. When the women were asked to estimate by weeks, 60 women responded: 3.3% (2/60) indicated that this event had occurred within 1 week of treatment; 6.7% (4/60) said within 1–2 weeks; and 13.3% (8/60) said within 3–4 weeks. In summary, 23.3% (14/60) of the women stated they inserted something into their vagina within 4 weeks and 76.7% (46/60) said they waited until after 4 weeks.

Treatment Side Effects

The women gave both verbal accounts and diary information regarding their first post-cryotherapy menses. For 95.5% (322/337) of the women who responded to the question, menstruation had occurred since cryotherapy; any change from their normal menses was subsequently recorded by 314 women. With respect to menstrual blood flow, 77.7% (244/314) of the women who responded had experienced *no change*; 6.4% (20/314) had *less* blood flow than normal; 13.4% (42/314) reported having *more* blood flow than normal; and 2.2% (7/314) had *significantly more* blood flow. Only 1 of the 314 (0.3%) claimed her flow was variable and thus could not be compared. Menstrual cramping had also changed for some women. Of the 307 women who responded, 2.0% (6/307) experienced *a lot less* cramping; 10.4% (26/307) experienced *less* cramping; 8.1% (25/307) experienced *more* cramping; and 0.7% (2/307) experienced *much more* cramping. Most of the remaining 76.5% (235/307) of the women indicated *no change* in cramping levels, and 4.2% (13/307) reported *no* cramping. The duration of menses changed after treatment for a minority of the 309 respondents. Only 5.5% (17/309) of these women said that they bled *less* than before; 11.3% (35/309) bled *more* than normal; and 0.6% (2/309) bled *significantly more* than normal. Overall, 82.2% (254/309) of these women reported that they had periods that lasted the same number of days before and after cryotherapy treatment.

Of the 324 women who responded to the question, bleeding not associated with menstruation was noted for 6.2% (20/324). Only 9 women provided an estimate of the number of days after cryotherapy that the abnormal bleeding occurred, which was anywhere from 5–105 days post-treatment. For just over half of the women—55.6% (5/9)—it occurred within 38 days after cryotherapy. For the remaining 44.4% (4/9), abnormal bleeding occurred after or equal to 6 weeks post-cryotherapy. When asked to estimate this bleeding by weekly increments, 10.0% (2/20) of the women claimed that the abnormal bleeding occurred within the first week post-cryotherapy; 25.0% (5/20) estimated abnormal bleeding occurred between 1–2 weeks post-cryotherapy; 10.0% (2/20) between 3–4 weeks; and 55.0% (11/20) after 4 weeks.

Three hundred eleven women provided information about blood clots (i.e., balls or clumps of blood) and pain/cramping episodes. Blood clots were noted by 2.3% (7/311) of the women; 28.6% (2/7) had experienced clots within the previous month; and the remaining 5 women (5/7 or 71.4%) had experienced blood clots more than 1 month prior to their first followup visit. Intermenstrual pain or cramping was experienced by 10.1% (32/316) of the women. Twelve women out of 32 who experienced pain or cramping reported timing of their pain by specific day; 5 of these women (41.7%) had experienced pain within 14 days post-cryotherapy, whereas 7/12 (58.3%) experienced the pain anywhere from 35–90 days post treatment. Twenty-eight women were able to identify the week when the pain began: for 28.6% (8/28), pain occurred in the first week post-treatment; for 10.7% (3/28), in weeks 1–2; in 3.6% (1/28), pain occurred in the third week; and for 57.1% (16/28) women, pain began after 4 weeks post treatment.

Twenty-eight women classified their level of intermenstrual pain. Their pain/cramping was described as *mild* for 28.6% (8/28), *moderate* for 42.9% (12/28), and *severe* for 28.6% (8/28). The pain/cramps were also compared to the women's worst menstrual cramps. Of the 35 respondents, 17.1% (6/35) claimed that these episodes were *less* painful; 8.6% (3/35) said that they were *a lot less* painful; and 17.1% (6/35) said that the episodes were *comparable* to their typical menstrual cramps. The intermenstrual pains/cramps were *a lot more* painful for 20.0%

(7/35) of the women; 20.0% (7/35) said they were *more* painful; and 17.1% (6/35) said that they could not be compared.

Of the 289 women who responded, 8 (2.8%) said that they had become pregnant since treatment, two of these pregnancies were recorded as having ended, one in abortion and the other was recorded as a live term birth. Thus, 2.1% (6/289) of these women were pregnant at the time of their first followup visit. One woman (0.3%) responded that she did not know if she had become pregnant since treatment. The remaining 96.9% (280/289) of the women claimed that they had not become pregnant or given birth since their treatment. When asked if they had experienced any other problems in the cervix, vagina or pelvic area since treatment, 1 (1/310 or 0.3%) woman who had been pregnant once before claimed that she had experienced problems trying to become pregnant.

Other than the problems covered above, 6 women had experienced one or more problems since their treatment, including: abnormal vaginal discharge (5.5% or 17/310), chills/fevers/hot sweats (1.3% or 4/310) (none of those presenting with chills/fever women are among the 5 who had a problem visit), and 11 women (3.5% of 310) had "other" problems. These problems included irregular bleeding (1 woman), irritation or itching in the vagina (4 women), delayed or no menses since treatment (2 women), painful intercourse (1 woman), spotting (1 woman), and unspecified problems (2 women).

When asked what measures were taken when such other problems arose, 6 of 109 women (5.5%) indicated that they had visited the same health facility as they did for their first followup visit. (Note that among the 5 people with a problem visit form, 2 indicated they had returned for a problem visit on the first followup form. Two did not have a first followup visit and 1 did not mention returning for a problem at her first followup visit). Eleven women (10.1% or 11/109) indicated that they had attended another health facility for a problem visit. Overall, 17.4% (19/109) of these women indicated that they had visited any facility post-treatment. None of the women indicated that they had visited a traditional healer or used traditional remedies. Four women (3.7%/109) used a pharmacological remedy. Two women reported taking a measure "other" than those listed, but one of these was unspecified and the other woman said it resolved itself.

Overall, the majority of women (66.8% or 225/337) reported no problems since treatment; 16.0% (54/337) did experience one problem; 10.4% (35/337) reported two problems; 4.2% (14/337) reported three; and 2.7% (9/337) reported four or more problems at the first followup visit.

Patient Perspectives

The majority of women who returned for their first followup visit (76.7% or 254/331) characterized their post-treatment experience as better than they had anticipated; 16.9% (56/331) said that the experience matched their expectations; and 5.1% (17/331) indicated that they did not have any expectations before the treatment. Only 1.2% (4/331) of the women believed their experience was worse than what they expected.

Most women felt that they had been sufficiently counseled. Women were asked, "Do you think that the staff counseled you enough about what to expect after treatment?" Of the 336 women who responded, 2.7% (9/336) said "mostly," and 97.3% (327/336) responded "very much so." With respect to particular aspects of the counseling, such as the expected side effects or risk-

associated behaviors, a maximum of 2 women (0.6% of 337) identified each specific issue as being inadequately addressed.

Women expressed high levels of satisfaction with the VIA test, and said that they would recommend it to their friends or family members. Of the 335 respondents who answered the question, 99.4% (333/335) indicated that they were either *very satisfied* (75.2% or 252/335) or *satisfied* (24.2% or 81/335) with their decision to have the condition of their cervix assessed using VIA. A small proportion (0.6% or 2/335) felt ambivalent about the decision. Of the women who responded, most indicated that they were either *very satisfied* (87.2% or 292/335) or *satisfied* (12.5% or 42/335) about their decision to be treated with cryotherapy for suspect cervical disease. Only 1 woman (0.3% of 335) was ambivalent or neutral about this decision. Of the 335 women who answered the question about recommending VIA, most (98.5% or 330/335) had already recommended to friends and/or family members that they get VIA tested. VIA had not yet been recommended to friends and/or family members by only 1.5% (5/335) of the women. All 5 of these women thought they would recommend the test in the future. (In fact, all [329/329] of the women who responded thought that they would in the future recommend that friends or family members get tested.) None of the women had a problem visit form, and only 2 mentioned any problem at the first followup visit (1 had more menstrual cramping and 1 had some non-menstrual bleeding).

Post-Treatment Partner Support

To aid in the assessment of treatment acceptability, questions concerning the supportiveness of women's husbands/partners were asked. Of the 315 respondents, 8.3% (26/315) said that they had problems trying to convince their husbands/partners to postpone intercourse for 4 weeks after treatment. Among the 26 who reported problems convincing their partners to wait, 57.7% (15/26) had sexual intercourse prior to 4 weeks post-treatment. Only 6.3% (17/269) of the women who reported no such problems had sexual relations prior to 4 weeks.

An additional 6.3% (20/315) of the women did not ask their husbands/partners to postpone intercourse. The majority—85.4% (269/315)—indicated that they did not have problems postponing intercourse. If they did have intercourse, the women were asked if they had any problems trying to convince their husbands/partners to use condoms.

The majority of respondents—78.0% (252/323)—felt that their husbands/partners were either *very supportive* (63.2% or 204/323), or *somewhat supportive* (14.9% or 48/323) about the need for abstinence and/or condom use for the designated time period post-treatment. Only 4.6% (15/323) of the respondents felt as though their husbands/partners were *not very supportive*, and 0.3% (1/323) felt that they were *not supportive at all*. A minority (6.3%) of the women indicated that they either did not have husbands/partners (6.2% or 20/323), or that their husbands/partners were not around post-cryotherapy (10.8% or 35/323).

Women were asked, "How do you think your husband/partner feels about your decision to receive treatment?" Of the 322 women who responded, 82.6% (266/322) claimed that they thought their husbands/partners were either *very satisfied* (57.8% or 186/322), or *satisfied* (24.8% or 80/322) with their decision. Only 1.6% (5/322) of the women said that their husbands/partners were ambivalent about their decision to receive treatment. Another 6.2% (20/322) of the women claimed not to have husbands/partners, and 9.0% (29/322) reported that their

husbands/partners were not around. Six women (1.9% of 324) indicated that they would like their husbands/partners to have received additional information.

Provider Perspectives

Providers were asked to assess whether or not they attributed any of the women's complaints or health problems to their cryotherapy treatments. According to providers, any health problems cited by the women were related to the treatment in only 3 cases (1.0% of 310). Further questions or concerns were recorded by 5.6% (18/321) of the women on the back of their questionnaires.

Because there were no indications of any major clinical problems due to the cryotherapy treatment at the time of the followup visit, no women had additional clinical assessments performed at the first visits. (This was the criterion in the clinical protocol that warranted a full exam at the first followup visit.)

ONE-YEAR FOLLOWUP VISIT

The protocol called for women to return to the clinic `1 year after cryotherapy treatment for a VIA assessment and general evaluation. This section describes the results from these final followup visits.

The questionnaire from this visit contained information similar to that recorded for the first followup visit—compliance with home care recommendations, potential treatment side effects, overall patient perspectives about their experience and post-treatment partner support. Of the 439 women who reported in the first (12–16 weeks) or 1-year followup that they underwent cryotherapy, 53.3% (234/439) returned for their 1-year followup visit by the time the data were analyzed (data collection ended 3 months after the last followup visit was scheduled to take place). Although 439 women reported receiving cryotherapy, cryotherapy forms were available for only 422 for this report.

PERSONAL QUESTIONNAIRE

Women who came for their 1-year followup and who had not presented for their first followup visit (N=20) were asked about the date of their first sexual intercourse post-treatment, the use of condoms, and the act of inserting anything into the vagina. Where appropriate, the responses of these 20 women have been added to the responses of those who answered the same questions during the first followup visit, yielding as the denominator all those responding to this set of questions during either of the two followup visits. Overall, a total of 359 women out of 439 (81.8%) who said they received cryotherapy responded to these questions at either their first or 1-year followup visit.

Women's Compliance with Home Care Recommendations

First Sexual Intercourse

At first followup, or at 1 year if there was no first followup, 247 women out of 356 (69.3%) indicated that they had had sexual relations post-treatment. Of these 247 women, 35 (14.2%) indicated that intercourse had taken place within 4 weeks of cryotherapy treatment (12.1% [30/247] between 3–4 weeks; 2.0% [5/247] between 1–2 weeks; and 0% [0/247] within 1 week). A total of 212 (85.9%) estimated that intercourse had occurred after 4 weeks post-treatment.

Combining both followup response periods, 25/35 or 71.4% women offered a main reason for why they had engaged in sex earlier than recommended: 6 (24%) said that they did not want to say no to or disappoint their husbands/partners; 15 (60%) said that their husbands/partners forced them; 2 (8%) said that their husband/partner threatened to have sex with others; 1 (4%) said that she was afraid their her husband/partner would have sex with others if she did not; and 1 (4%) had an unspecified reason for initiating sexual intercourse early. No women said that they wanted to have intercourse, that they were not convinced that this time period was important, or that they forgot about the waiting period.

Condom Use

Many of the women who had had sex (89.8% or 219/244) said that they used condoms during intercourse after treatment. Among the 219 who used condoms, 217 were able to estimate this time in weeks. The majority (85.3% or 185/217) estimated that they used condoms after 4 weeks post-treatment; 13.4% (29/217) estimated that condom use began between 3–4 weeks; and 1.4% (3/217) estimated 1–2 weeks.

Of the 35 women who report having sex in the first 4 weeks after treatment, 94.3% (33/35) reported condom use. Each woman who used condoms reported having begun condom use in the same period in which she first had intercourse after treatment. Two of these women did not report their use regularity. Among those who did answer, 81.8% (27/33) used condoms all of the time, 9.1% (3/33) most of the time, 3.0% (1/33) some of the time, and 6.1% (2/33) never used condoms. Among the 6 women who had sex prior to 4 weeks and who did not use condoms all of the time, 2 reported that their husband/boyfriend refused to use them; 1 woman used condoms during sex until 6 weeks and then stopped; and 3 women did not specify why they had not used them all of the time.

Vaginal Insertion

Each woman was asked, "Have you inserted anything into your vagina in the interim since treatment?" In total, 353 out of 439 women responded to this question, and 17.8% (63/353) answered "yes." Among the 63 women who had inserted something, 62 were able to estimate the week this occurred after treatment: 3.2% (2/62) estimated this happened in the first week after treatment; 6.5%(4/62) said it occurred in weeks 1–2; 12.9% (8/62) estimated that it occurred 3–4 weeks post-treatment; and the remaining 77.4% (48/62) estimated that it occurred after more than 4 weeks post-treatment.

Treatment Side Effects

Menstruation, Non-Menses Bleeding, and Pain/Cramping

The majority (95.5% or 340/356) of the women who responded indicated that they had menstruated since their treatment. Also, 6.4% (22/342) indicated that they had experienced bleeding unrelated to menses, including post-coital bleeding, since treatment. Most (54.5% or 12/22) who responded about timing said that non-menses bleeding occurred after the first 4 weeks following cryotherapy. Two women (9.1% of 22) said that they had bled within the first week post-cryotherapy; 22.7% (5/22) said within 1–2 weeks post-cryotherapy; and 3 women (13.6% of 22) said within 3–4 weeks post-cryotherapy.

Pain/cramping not associated with menstruation was noted for only 10.5% (35/334) of those who responded to this question. Of the 31 women who indicated the duration of this pain, it lasted less than 1 week for 25.8% (8/31), 1–2 weeks for 12.9% (4/31), 3–4 weeks for 6.5% (2/31), and more than 4 weeks for 54.8% (17/31). Of the 30 women who responded about the severity of the pain/cramping, it was described as *mild* by 26.7% (8/30), *moderate* by 46.7% (14/30), and *severe* by 8 women (26.7%).

Pregnancy

Five women (1.6% of 305) indicated that they became pregnant and the pregnancy had ended, and 2.0% (6/305) were still pregnant. The majority of the 305 women (95.4% or 291/305) had not become pregnant since their treatments; 0.7% (2/305) indicated they had not become pregnant and were using contraception; and 0.3% (1/305) answered "not that I know of" to the question of whether or not they had become pregnant. The status of the 11 pregnancies was: 4 resulted in live, full-term births; 1 pregnancy was aborted; and 6 women were still pregnant at the time of the followup visit.

Other Problems

Of 329 women who responded about "other" problems they had experienced, 5 (1.5% of 329) claimed they had problems getting pregnant; 20 (6.1% of 329) indicated they had experienced abnormal offensive vaginal discharge; 5 (1.5% of 329) said they experienced chills, hot sweats, and/or a fever; and 14 (4.3% of 329) indicated they had another, unspecified problem since their treatments.

Combining all questions where a problem could be recorded (i.e., if they had a problem visit form, any non-menses bleeding, pain/cramp, any problem getting pregnant, any discharge, chills, or other problems, if they came back to the facility or went somewhere else, or used a pharmacy, traditional medicine, or other ways to treat a problem), there were 86/321 (26.8%) women who reported somewhere that they had a problem.

Women's Perspectives

When asked to characterize their experience after treatment, 337 to 357 women responded to each question: 76.1% (268/352) indicated the experience was better than expected; 16.8% (59/352) said the experience met their expectations; and 6.0% (21/352) said they had no expectations of the visit. Only 1.1% (4/352) of the women said the experience was worse than they had expected. When asked whether they were counseled enough about what to expect after treatment, 96.9% (346/357) said "very much so," and 3.1% (11/357) said that they were counseled "mostly" enough. When all of the women were asked on what topics they would have liked more counseling, 0.6% (2/337) of the respondents said that they would have liked more information about the amount of pain/cramping that was to be expected, and 0.6% (2/337) said that they wanted more information about the duration of such pain/cramping. With regard to vaginal discharge, women said that more counseling should be provided about: the expected amount (0.3% or 1/337), its duration (0.3% or 1/337), and its odor (0.3% or 1/337). Other women felt that there should have been more counseling about the need for abstinence (0.3% or 1/337), condom use (0.3% or 1/337), the risks of inserting anything into the vagina (0.6% or 2/337), and the warning signs associated with the treatment (0.3% or 1/337).

The majority of the 356 women who responded were either *very satisfied* (74.4% or 265/356) or *satisfied* (25% or 89/356) with their decision to have the condition of their cervix assessed with the VIA test. Two women (0.6% of 356) said that they were neutral about this decision. Most of the women (98.6% or 351/356) had recommended the VIA test to their friends or family members, and 100% (350/350) indicated that they would do so in the future. The majority of the women were either *very satisfied* (86.5% or 308/356) or *satisfied* (13.2% or 47/356) with their

decision to undergo cryotherapy. One woman (0.3% or 1/356) said that she was neutral about this decision.

Post-Treatment Partner Support

Of the 333 women who said that they resumed intercourse after their treatment and provided answers to the question, 8.1% (27/333) said that they had problems trying to convince their husbands/partners to postpone having sexual intercourse. Another 6.0% (20/333) of the women said that they did not try to ask their husbands/partners to postpone having intercourse. Overall, 84.7% of these women (282/333) did not have any problems trying to convince their husbands/partners to postpone having intercourse after treatment. Four women (1.2% of 333) claimed that their husbands/partners were not around.

Of the 341 women who said that they resumed intercourse after their treatment, 8.8% (30/341) said that they had problems trying to convince their husbands/partners to use condoms. Another 0.9% (3/341) of the women said that they did not try to ask their husbands/partners to use condoms. Overall, 69.2% of these women (236/341) did not have any problems trying to convince their husbands/partners to use condoms after treatment. Seventy-two women (21.1% of 341) claimed that they did not have sexual relations.

When asked, "How supportive would you say your husband/partner was about the need for abstinence/condom use after treatment?" the majority of women (63.5%or 216/340) stated that their husbands were *very supportive*. The remaining women claimed their husbands/partners were *somewhat supportive* (14.7% or 50/340), *not very supportive* (4.4% or 15/340), *not supportive at all* (0.6% or 2/340), they had no husband/partner (5.9% or 20/340), or their husbands/partners were not around (10.9% or 37/340).

When asked, "How do you think your husband/partner feels about your decision to receive treatment?" the majority (57.1% or 194/340) of the women who responded felt their husbands were *very satisfied*. Eighty-seven women (25.6% of 340) responded they felt their husbands were *satisfied*, 6 women (1.8% of 340) felt their husbands/partners were *neutral*, 1 woman (0.3% of 340) felt her husband/partner was *unsatisfied*, and 1 woman (0.3% of 340) felt her husband/partner was *very unsatisfied*. Twenty women (5.9% of 340) claimed to have no partner, and 31 women (9.1% of 340) claimed her husband/partner was not around.

As a final question, the women were asked if there was any additional information they would have liked their husbands/partners to receive, and 1.8% (6/341) said that there was.

HEALTH CARE PROVIDER INFORMATION

After the interviews, the nurses examined the women, performed VIA, recorded the results, and provided followup care for any women who required it.

Of those assessed at 1 year (234 women in total, but for results, data are missing for 2 women), the results of their VIA tests were as follows: 0.0% (0/232) were assessed as having suspect cancer; 2.6% (6/232) were VIA test-positive; 95.3% (221/232) were VIA test-negative; and for 2.2% (5/232), the health care workers were unable to complete the VIA test.

How many had SCJ visible?

The SCJ was visible in 227 women (97.8%) at 1 year. In 3 women (1.3%), the SCJ was not visible and located in the cervical canal; in 2 (0.9%) the SCJ was not visible due to pregnancy; and data were missing for 9 women. Of the 6 women who were test-positive, it was recorded that 4 women did not have any of the listed manageable or referable conditions, such as polyps or abnormal uterine bleeding. For the other 2 there was no response to any of those questions. For these same 4 women, the health care providers indicated "none of the above" for extending more than 2 mm beyond the probe, beyond the vaginal wall, or greater than or equal to 75%. Three women (3/3 or 100%) who responded and were eligible for treatment were agreeable to immediate treatment. It was indicated that none of these women's treatments were postponed or referred elsewhere.

DISCUSSION

The results of this project demonstrate that a single visit approach linking VIA testing with the offer of cryotherapy treatment is:

- *Safe*—There are minimal complications.
- *Acceptable*—Women will come for testing when it is offered if they know that good followup care is likely, and they will recommend the service to others.
- *Feasible*—Trained, supervised nurse-midwives can safely provide testing and treatment in a low-resource setting, and the health facility can accommodate testing, treatment, and referral services.

Moreover, this approach can also result in low referral of test-positives 1 year post-treatment.

The results of this demonstration project provide important *safety* information for developing-country policymakers considering how to strengthen fledgling cervical cancer prevention programs. According to all available followup data, no clinically apparent pelvic inflammatory disease (PID) or cervical stenosis occurred as a complication of cryotherapy. Moreover, the overall rate of minor complications resulting from cryotherapy performed by a trained nurse-midwife was low (5.5%). It is possible that more problems post-cryotherapy went unreported because of access issues among treated women.

A SVA linking VIA and cryotherapy appeared to be *acceptable* not only to women, but also to their partners and to the service providers. Other, more qualitative methods of measuring acceptability would provide further insights into how acceptable the service was and what aspects may be in need of attention. Results of such a qualitative assessment have been reported separately (Corneli et al. 2004).

This experience in Ghana also demonstrates that it is *feasible* to maintain programmatic logistics, for example, refilling the carbon dioxide tanks. The relatively low number of working parts of the cryotherapy unit (that could malfunction) as well as targeting of training in equipment care and maintenance contributed to the ability to maintain these units in the field. There were very few treatment postponements for clinic-related reasons, which suggests that supply could meet the demand for services.

The 1-year scheduled return visit rate was relatively low, which reflected problems in the urban area with facility access, time constraints, and motivation. Considerable effort was required by the project team to increase both first and final visit followup rates. Adherence to the home care requirements was relatively high.

The majority (84%) of project women reported that they arrived at the facility within 60 minutes travel time, and 42% traveled for less than 30 minutes. Therefore, these results reflect use of services by women living relatively close to Ridge Hospital. Very few (2%) of participants reported ever having had a Pap smear in the past (compared to the estimated overall rate in Ghana of approximately 5%), suggesting that the project results in this regard are likely representative of women in both urban and rural Ghana. That almost 50% of women had completed up to 11 years of schooling reflects the urban focus of the project.

Because this demonstration project was designed to test the SVA as it would actually be implemented in a low-resource country, VIA was the only disease status obtained before treatment (Blumenthal et al. 2001). Therefore, actual treatment cure rates were not measurable. However, acetowhite lesions 1-year post-treatment provide an indication of the need for re-treatment (and/or referral) and can be easily measured and monitored under non-research program conditions (e.g., as part of a routine quality assurance system).

Importantly, among test-positive women who received cryotherapy treatment and who also returned for the 1-year followup visit, their test-positive rate at 1 year was only 2.6%. Given that the negative predictive value of VIA has repeatedly been reported as 96% or greater, the low test-positive rate measured at 1 year is an important assurance to policymakers that cancers were not misdiagnosed in the first place (Belinson et al. 2001; Megevand et al. 1996; Sankaranarayanan et al. 1999; University of Zimbabwe/JHPIEGO Cervical Cancer Project 1999).

It is noteworthy that in 97.8% of those treated, the SCJ was visible to the nurse-midwives 1 year later. A commonly held opinion regarding the disadvantages of cryotherapy is that, after the ablative procedure, the SCJ recedes into the cervical canal, is no longer visible, and therefore cannot serve as a landmark for the detection of precancerous lesions. The reason for our findings may be that in many assessments of cryotherapy undertaken primarily in the United States or Europe, younger, often nulliparous women were involved. In experiences among older, more parous women, the SCJ initially appeared to be well out on the face of the exocervix, such that even after cryotherapy had been performed and the cervix healed, the SCJ remained visible and further assessment by VIA was possible.

For many years, Ghana has struggled to implement a cervical cancer prevention program based on a "test and refer" approach (i.e., cytology-based testing and referral of all test-positives for additional diagnostic tests, including biopsy and treatment, if indicated). National annual Pap smear screening coverage is low and treatment for women with precancerous lesions is available only in selected hospitals. Although work exploring the potential of VIA combined with cryotherapy in rural areas is needed (currently ongoing in a second, rural SAFE Project in Amasaman subdistrict of the Ga District) as well as continued experience in Ridge Hospital to answer questions related to cost, sustainability, and cryotherapy effectiveness in the hands of non-physicians, the results of this project indicate that a SVA based on VIA and cryotherapy and performed by nurse-midwives is safe, acceptable, and feasible. As such, and in light of the mounting cost-effectiveness data on the SVA, it should be considered an alternative for high-risk areas where the likelihood of successfully implementing a more traditional approach to cancer prevention is low (Goldie et al. 2001; Mandelblatt et al. 2002).

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