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

Outcomes Research Study on Cervical Cancer Prevention and Treatment: Results from Ghana

FEBRUARY 2008

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Funding from the
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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
CI	Confidence intervals
HLD	High-level disinfect, disinfected or disinfection
IARC	International Agency for Research on Cancer
MOH	Ministry of Health
SAFE	Safety, Acceptability, Feasibility, and program Effort
SCJ	Squamo-columnar junction
SVA	Single visit approach
VIA	Visual inspection with acetic acid

EXECUTIVE SUMMARY

From 2006 to 2007, JHPIEGO, in conjunction with the Ghanaian Ministry of Health, conducted the Outcomes Research Study on Cervical Cancer Prevention and Treatment. This operations research study sought to examine the extent to which the quality of cervical cancer prevention and treatment services was maintained after external funding had been removed in Ghana and Thailand—two countries with Cervical Cancer Prevention (CECAP) programs that had previously received significant external financial support. The methods employed in the study included independent co-assessments of provider skills, assessments of provider performance using a detailed checklist, and interviews with providers. This report presents results obtained in Ghana; results from the Thailand study are reported separately.

The key outcome measures of this research included the level of agreement in clinical decision-making between Ghanaian providers of cervical cancer services and a "reference standard observer," who made independent assessments of the same clients seen by providers. The average level of agreement between the observers and providers, both in the diagnosis of the cervix through visual inspection with acetic acid (VIA) and the case management decision based on that diagnosis, was in the "almost perfect" range—with the Kappa of 0.87 for diagnosis (95% CI 0.77–0.97) and 0.92 for the case management decision (95% CI 0.85–0.99). Similarly, assessment of provider performance according to a standards checklist showed a high level of performance, with average scores of 99% for screening using VIA and 98% for treatment using cryotherapy.

Provider interviews revealed a heavy dependence on peer support as a mechanism for maintaining quality of CECAP services. This is understandable in the Ghana context, where national-scale supervision systems and other formal means of support for services (e.g., materials, supplies, registers) have not yet been established.

Overall, findings were notable with regard to the high level of quality maintained by providers in a context of relatively low external support.

BACKGROUND

Cervical cancer is the second most common cancer among women globally. Each year, there are approximately 493,000 new cases of cervical cancer—almost 80% of which occur among women living in developing countries—and more than 274,000 women die of the disease (Ferlay et al. 2004). But cervical cancer need not be fatal. Most of these deaths can be prevented by the widespread application of cervical cancer screening and, when appropriate, treatment of precancerous lesions.

In sub-Saharan Africa, cervical cancer is the most common cancer of women. In West, East, Central and Southern Africa, cervical cancer accounts for an estimated 20–25% of all new cancers among women (est. IARC 1990). Because effective screening and treatment services are scarce or nonexistent in countries with limited resources, such as Ghana, many women continue to suffer from cervical cancer—having little understanding of the disease, the modes of its transmission and the means of its prevention.

Ghana is a West African country of 22 million people. Reproductive health indicators show a strong need for improvement—with a contraceptive prevalence rate of 25%, only 47% of births attended by a skilled health care provider and a lifetime risk of maternal death of one in 35 (UNICEF 2008). In 2000, the International Agency for Research on Cancer (IARC) reported that of 6,176 cancers in women surveyed in Ghana, 1,307 (21.2%) were cervical cancer; of 3,720 deaths from cancer in women, 672 (18%) were from cervical cancer (Ferlay et al. 2001). A limited survey done in the 1980s by the Ghana Medical Service in the Greater Accra Region found that of 4,215 women with cancer, 902 (21%) had cervical cancer.

Cervical cancer screening is rare in Ghana. Until 2000, the Pap smear test was the only form of screening available in the country. It was virtually unknown to the general population of women, however, because of limited availability of supplies needed to perform the test and of locations where it is offered. Korle Bu Hospital reported that 1,500 Pap tests were performed at the hospital in 1999. Some private clinics have also offered the test, but no information has been systematically collected from these sites.

Provider Performance as Maintained by Programmatic Inputs

While recent studies have looked at mortality and morbidity related to the introduction of cervical cancer prevention and treatment in lower resource settings (Sankaranarayanan et al. 2007a), less work has been done to look at the specific program elements that allow for provision of high-quality cervical cancer screening and treatment programs. The Outcomes Research Study sought to answer the following questions: "Was a high level of quality maintained in the performance of the providers?" and "What were the means by which quality was maintained?"

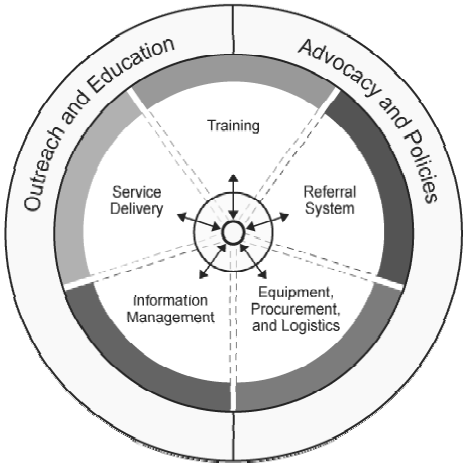
To understand the findings of this research, then, one must understand the programmatic context in which it is placed. The JHPIEGO-led Cervical Cancer Prevention (CECAP) program was run by nurses in family planning clinics at three diverse health facilities in Ghana. Ridge Hospital is a large urban hospital in Accra, Kumasi South Hospital also serves an urban clientele (Kumasi being the second largest city in Ghana), and Amasaman Health Centre serves a peri-urban community. The CECAP program had been integrated with services offered at the family planning clinics in each of these sites to reach the widest number of clients, while adhering to national policies and recommendations around provision of screening and treatment services. Services were provided by

nurses and nurse–midwives who worked in the family planning clinics. While no outreach services were provided off-site, providers made trips to surrounding communities and community groups to raise awareness of the services available and to encourage women to access them.

One of the most relevant findings of this report is the feasibility of integrating cervical cancer prevention services—including cervical cancer screening through visual inspection with acetic acid and treatment of precancerous lesions with cryotherapy—with existing reproductive health services, namely family planning. The 13 nurses providing cervical cancer prevention services through the single visit approach were able to successfully integrate these services with those offered at very busy family planning clinics. At the clinics' highest client volume, individual providers were seeing as many as 62 CECAP clients per month—in addition to providing all of the other usual services offered through the clinic.

A key component of any screening program is achieving sufficient coverage to realize a long-term impact on morbidity and mortality, generally considered to be 70% or higher (Duncan 1997; Monsonego 1997). In England, for example, a significant decline in national mortality rates occurred only after 80% coverage was exceeded (Duncan 1997). The interval at which screening should be conducted is dependent on available resources and desired mortality reduction. One study showed that screening 50% of women aged 35–64 every five years led to a 42% reduction in cumulative incidence of cervical cancer, while screening 80% of women every 10 years led to a reduction of 51% (Monsonego 1997).

Exhibit 1: Program Components for a Single Visit Approach to Cervical Cancer Prevention



The extraordinary program in Ghana provides some evidence that individual providers can serve a large number of clients. Theoretically, with a larger number of trained providers, significant coverage of clients could be achieved. Successful programs in Thailand and Malawi, as well as this program in Ghana, have relied heavily on systematized program management principles. **Exhibit 1** shows the components that must be in place to develop a successful screening program.

Ghana SAFE Project

From early 2000 through July 2003, the Ministry of Health (MOH)/Ghana Health Service (GHS), in partnership with JHPIEGO, implemented a Safety, Accessibility, Feasibility, and program Effort (SAFE) demonstration project, which was locally referred to as Cervicare. The objective of this project was to rigorously assess the "single visit approach" (SVA) to cervical cancer prevention, using visual inspection with acetic acid (VIA) for screening linked to the immediate offer of cryotherapy for treatment of precancerous lesions when appropriate, as an alternative to a cytology-based cervical cancer prevention program. VIA is a simple procedure that consists of swabbing the cervix with a dilute solution of acetic acid (vinegar), waiting for one minute and then viewing the cervix with a light source. Precancerous lesions are suspected if acetowhite changes appear near the squamo-columnar junction (SCJ). If lesions meet all established criteria (e.g., occupy less than 75% of the surface area of the cervix), the woman is offered the option of immediate treatment with cryotherapy.

To implement the SAFE/Cervicare project, two sites were selected: Ridge Hospital, a public hospital in the urban center of Accra, and Amasaman Health Centre, a semi-rural, sub-district health center in the Greater Accra Region. At Ridge, the project tested and collected data on 3,665 women between 26 March 2001 and 31 July 2003. At Amasaman, 3,225 women were tested between December 2001 and 31 July 2003. The Cervicare project measured specific indicators of safety, acceptability and feasibility, which are reported separately (Corneli et al. 2004).

Scale-Up Efforts

Although the SAFE study concluded in 2003, JHPIEGO continued to support VIA and cryotherapy service delivery at Ridge Hospital and Amasaman Health Centre through December 2004 and also trained four additional providers and established CECAP services at Kumasi South Hospital. From 2004 to 2006, screening for clients continued in these three sites with the support of Ghana's MOH. The figures for numbers of clients screened, VIA test-positives found, cryotherapy treatments performed and cases of cancer suspected are provided in **Exhibit 2**.

Exhibit 2: Cervical Cancer Prevention and Treatment Services at Ridge, Amasaman and Kumasi South, 2001–2006

Year	Total Clients Screened	Total VIA+	VIA+ Rate	Total Cryos Performed on Day of Diagnosis	Total Cryos Performed after Day of Diagnosis*	Overall Total of Cryos Performed	Total Cases of Suspected Cancer
2001	2,976	350	11.76%	211	88	299	5
2002	4,977	554	11.13%	318	227	545	3
2003	5,278	302	5.72%	195	102	297	7
2004	1,432	46	3.21%	21	25	46	1
2005	2,738	255	9.31%	158	94	252	0
2006	2,102	157	7.47%	64	84	148	0
Total	**19,503**	**1,664**	**8.53%**	**967**	**620**	**1,587**	**16**

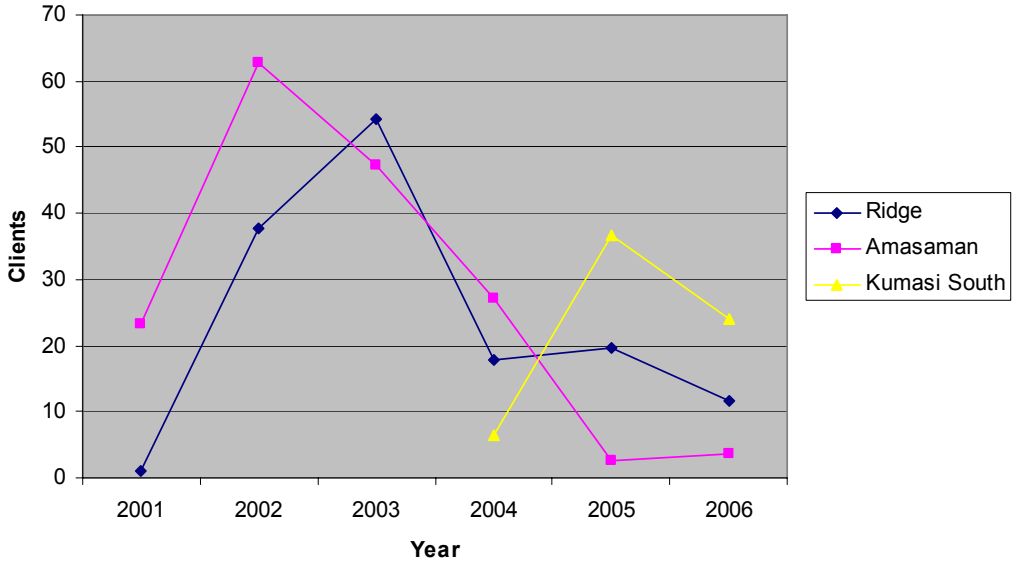
*Clients were provided the option of receiving immediate cryotherapy or returning for their cryotherapy at a later date, after discussing with family members first.

In addition to the number of women screened, the number of clients per month per provider was examined. Findings are presented in **Exhibit 3**. It is notable that in all three facilities, the peak number of clients per provider per month was reached between one and two years from the start of the program, followed by a decline. Anecdotal reports from providers suggest that this peak corresponded with outreach efforts, indicating that at least in Ghana, client outreach via media outlets and visits to communities and community groups may have had a positive impact on client volume. The largest volume of clients per provider per month was reported at Amasaman Health Centre (62 clients), followed by Ridge Hospital (54 clients) and then Kumasi South Hospital (38 clients).

By 2006, several years after the SAFE/Cervicare project ended, the number of clients had declined dramatically in all of the facilities. Ghanaian counterparts attribute this decline in clients to two main

factors. First, the SAFE project had supported active outreach to new clients, including radio and television announcements and providers speaking to women's groups. Second, after SAFE, the facilities had to introduce small fees (under US$2 per screening) to help cover costs of the services.

Exhibit 3: Average Workload per Month per Provider, 2001–2006



Operations Research

From December 2005 to February 2007, JHPIEGO, funded by the Bill & Melinda Gates Foundation, conducted an operations research study to evaluate whether the level of performance of providers delivering CECAP services had been maintained after external funding had been withdrawn, and to determine what programmatic methods were used to help maintain quality of services. The results of this evaluation are reported here.

LITERATURE REVIEW

The effectiveness of a screen-and-treat approach (i.e., SVA) to cervical cancer prevention in low-resource settings has been well-documented (Belinson et al. 2001; Denny et al. 2002; Gaffikin et al. 2003; Mandelblatt et al. 2002; Sankaranarayanan et al. 2007b). However, there is little data on the long-term programmatic performance—including sustained quality of services—of VIA-based screening programs.

The level of diagnostic concordance between two providers is a useful and efficient measure of performance (Cibas et al. 2001). Multiple studies have looked at concordance in diagnosis in relation to Pap smears. Studies looking at quality assurance in cytology-based screening have found that even among well-trained pathologists, there is a degree of irreproducibility in diagnostic interpretations of specimens (Collaco et al. 2005; Stoler et al. 2001).The disagreement has ranged from 0.18% in a sample of 2,124 Pap smears, to 3.2% in 20,000 Pap smears and 2.96% in a sample of 65,753 Pap smears.

Although there have not been many comparable studies looking at quality assurance in VIA-based screening, it is clear that the training of service providers is a key factor affecting the reliability of the

VIA test and the quality of screening services. Even though individual performance may vary despite similar training, it is important to bring about standardization of VIA skills and provide quality training for health workers—so as to enable them to accurately diagnose the cervix and make appropriate case management decisions (Elit et al. 2006; Juneja et al. 2007; Mahe and Gaffikin 2005). The SAFE study in Ghana followed a rigorous training process, which has been described elsewhere (Blumenthal et al. 2007).

In the present study, we aimed to assess whether quality had been maintained in services delivered by service providers who had been trained through the SAFE/Cervicare project and follow-up efforts and are now implementing the CECAP program in Ghana. By performing multiple observations of a provider diagnosing the cervix and making a case management decision, and comparing these findings with a "reference standard" diagnosis and case management decision (those made simultaneously and independently by a "reference standard observer"), we attempted to characterize the quality of the diagnoses and decisions made by the providers.

METHODS

This study employed and reports on the following methods, which reflect the three main arms of the study:

1. Repeat co-assessments of the cervical diagnoses and case management decisions of these providers compared to a reference standard
2. Observations of providers as they provided VIA and cryotherapy services using a checklist of desired performance standards
3. Interviews with service providers providing cervical cancer prevention services and their supervisors on measures taken to maintain quality of services

Exhibit 4 below shows the types of data collection tools and the number completed at each of the three participating health facilities.

The study was conducted with ethical oversight from Western Institutional Review Board. This section further describes the methods used.

Exhibit 4: Number of Data Collection Tools Completed, by Type of Tool and Facility

Health Facility	Provider Interviews	VIA Performance Standards Achievement Observations	Cryotherapy Performance Standards Achievement Observations	Independent Co-Assessment of VIA
Ridge	6	6	3	148
Kumasi South	4	4	3	65
Amasaman	3	3	3	75
Totals	**13**	**13**	**9**	**288**

Method 1. Co-Assessments of Diagnosis and Case Management Decisions
This section of the study looks at the reliability of repeat measures for diagnosis of the cervix and case management of the cervical cancer screening client. Again, by performing multiple observations of a health services provider who is diagnosing the cervix and making a case management decision, and comparing these findings to a reference standard diagnosis and decision, we are able to evaluate provider performance on these tasks with a high degree of certainty.

The repeat measures on the diagnosis of the cervix and case management decision, as well as calculation of the Kappa, were chosen for this study because we wanted to evaluate provider performance with a higher degree of statistical relevance than the observations would allow, given that the group of providers in Ghana is very small. The repeated independent co-assessments allowed us to achieve this end. The Kappa helps show that the agreement reached between the two providers was not due to chance, but rather reflects a real level of agreement between the provider and the reference standard observer.

To make these measurements assessing the reliability of cervical diagnoses and case management decisions made by the providers, an independent co-assessment was used. When the provider saw the client, she reported the diagnosis and case management decision on her data form without consulting the reference standard observer and without allowing the observer to see her decision. The reference standard observer screened the same client as the provider and simultaneously and independently came up with a diagnosis and case management decision, which were recorded on a separate form.

Each provider was co-assessed in this manner multiple times. The goal was to co-assess each of the thirteen providers with 30 different clients, so as to have 30 standard/provider agreement "pairs." These pairs were then compared to determine the level of agreement. The figure of 30 clients was determined in consultation with a statistician who calculated the Kappa statistic with the team. (More information on sample calculation is included in **Appendix 1**.) Due to low client volume, the actual number of clients co-assessed was lower (average of 25 clients per provider in Ridge and Amasaman, and average of 16 clients per provider in Kumasi South).

As per the protocol for recording VIA in Ghana, both the provider and observer drew a map of the observed cervix, centered on the cervical os and showing visualized lesions or other pathologies. The two judgments that the providers and the reference standard observer made on the form were:

- VIA diagnosis (options: negative, positive or suspect cancer);
- Case management decision (options: counsel to return after five years, cryotherapy or referral).

Further information on coding of the data for calculation of the Kappa is included in **Appendix 2**.

Participants in the Co-Assessment: Providers were included in the study if they were currently providing services at Ridge Hospital, Amasaman Health Centre or Kumasi South Hospital, and were either part of the original cohort of providers trained, or among those trained as part of the roll-out of the study. The total number of providers co-assessed was 13, including six providers at Ridge, three at Amasaman and four at Kumasi South. There were two reference standard observers, including: a nurse with over seven of years of experience in conducting VIA, who has acted as JHPIEGO's in-country CECAP program manager for the past year; and a gynecologist, also with extensive expertise in VIA, who has served as a trainer of trainers in CECAP courses.

A total of 288 clients were observed as part of this study. Following Ghana's public health policy, clients were screened using VIA. If results were positive (meaning that cancerous or precancerous lesions were identified), clients were offered immediate cryotherapy (for precancerous lesions) or referral (for suspected cancer). If results were negative, clients were counseled to return for a five-year follow-up screening. If there was a difference between the diagnosis and case management decision made by the provider and those made by the reference standard observer, the client received the appropriate case management according to the reference standard observer's judgments (after the independent co-assessment was conducted and recorded).

Method 2. Performance Standards Achievements
Providers were assessed on their performance standards for both cryotherapy and VIA using an assessment tool that outlines all of the steps for providing these services according to a high standard of care. The tool was developed with facilitation by JHPIEGO along with a team of international and Ghanaian technical experts, adapted from training materials for teaching VIA and cryotherapy.

For the performance standards achievements, providers were observed by two trained researchers who are experts in cervical cancer service provision (a gynecologist and a nurse). Providers conducted their normal routine for VIA and cryotherapy, and were observed using a performance standards checklist. Unlike the Kappa calculations described above, providers were only observed once for the performance standards.[1] All 13 providers were observed performing VIA and/or cryotherapy. Only eight providers were observed conducting cryotherapy, due to the infrequency of the procedure; one provider was observed performing cryotherapy only.

Method 3. Provider Interviews
Of the 13 Ghanaian providers of CECAP services, 12 were interviewed (one was not reachable at the time of interview). The questionnaire focused on what methods were employed within the health facility to provide quality control for the CECAP services, including external review, supervision, clinical updates, peer review and client input.

RESULTS

Results 1. Co-Assessments of Diagnosis and Case Management Decisions
Exhibit 5 provides an overview of cervical diagnoses (through VIA) and case management decisions for all 288 clients in the study, from the perspective of the reference standard observer. The anticipated VIA test-positive rate was approximately 10%, but it was found that this particular pool of clients had a rate of approximately 6%. There were no cases of suspected cancer in the pool of clients. The two VIA results of "other" were for clients whose results were deemed "unreadable"; one was referred for further care, and the other was to be followed-up in two weeks. For the five clients coded as "missing" for their VIA result, three had Nabothian cysts to be treated before further testing, one had cervicitis and one had a fibroid that distorted the cervix. The six "referrals"

[1] Due to a sampling error in the early stages of the study, some of the providers were observed twice using the VIA performance standards. In these cases, the first of the two observations was selected and used in the analysis. A comparison was done that revealed no significant differences between the first and second observations for those providers who had been observed twice.

that occurred as the case management decision were thus not for suspected cancer but for other conditions requiring further care.

Exhibit 5: Diagnosis and Case Management for All Observed Clients According to Reference Standard Observer

	Ridge Hospital *N* (%)	Amasaman Health Centre *N* (%)	Kumasi South Hospital *N* (%)	Overall *N* (%)
Clients (*N*)	148	75	65	288
VIA Diagnosis				
Other	2 (1.4)	0 (0)	0 (0)	2 (0.7)
Negative	135 (91.2)	69 (92.0)	61 (93.9)	265 (92.0)
Positive	10 (6.8)	3 (4.0)	3 (4.6)	16 (5.6)
Suspected Canc.	0 (0)	0 (0)	0 (0)	0 (0)
Missing	1 (0.7)	3 (4.0)	1 (1.5)	5 (1.7)
Case Management				
Other	6 (4.1)	3 (4.0)	1 (1.5)	10 (3.5)
5-Yr. Follow Up	131 (88.5)	66 (88.0)	59 (90.8)	256 (88.9)
Cryotherapy	10 (6.8)	3 (4.0)	3 (4.6)	16 (5.6)
Referral	1 (0.7)	3 (4.0)	2 (3.1)	6 (2.1)
Missing	0 (0)	0 (0)	0 (0)	0 (0)

Exhibit 6 presents level of agreement between the providers and the reference standard observer at each of the three facilities and overall, both for the cervical diagnosis (VIA test result) and the case management decision.[2] As shown, the overall Kappa for the VIA diagnosis was 0.87 (95% CI = 0.77–0.97), while the overall Kappa for the case management decision was 0.92 (95% CI = 0.85–0.99). The range of the Kappas was 0.82–1.0. Even the lowest figure in this range falls in the "almost perfect" category as described by Landis & Koch (1977). The Kappas observed at each facility and overall indicate excellent agreement between providers and the reference standard observer for both the VIA diagnosis and the case management decision.[3] In addition, the Kappas for the different health facilities suggest that the cervical cancer screening program is similarly well-implemented at all three sites.

[2] Kappa provides a measure of agreement that is corrected for the level of agreement that would be expected based on chance. For example, if a person flips two coins at the same time, each coin has a 50% chance of landing on "heads" versus "tails," so the chance of "heads" for both coins is 0.50 x 0.50 = 0.25. After flipping both coins 100 times, one would expect them to both land on "heads" 25% of the time, both land on tails 25% of the time, and be mixed 50% of the time. If one conducted these 100 trials and observed both coins landing on heads 35% of the time, the Kappa would be (.35 - .25)/(1.00 - .25) = 0.13 (after removing the "chance").

[3] Landis & Koch (1977) give the following valuations for various levels of Kappa:

< 0 = poor
0.01–0.20 = slight
0.21–0.40 = fair
0.41–0.60 = moderate
0.61–0.80 = substantial
0.81–l.00 = almost perfect

Appendix 3 provides more information on the confidence intervals associated with the Kappa statistic. **Exhibit 7** presents the agreement and discrepancies in judgment between providers and the reference standard observer—this is the table by which the Kappa was calculated.

Exhibit 6: Kappas and 95% CIs for VIA Diagnosis and Case Management

Site	Kappa for VIA Diagnosis (CI)	Kappa for Management Decision (CI)
Ridge Hospital (6 providers, 148 clients)	0.89 (0.76–1.00)	0.91 (0.81–1.00)
Amasaman Health Centre (3 providers, 75 clients)	0.82 (0.58–1.00)	1.00 (1.00–1.00)
Kumasi South Hospital (4 providers, 65 clients)	0.88 (0.65–1.00)	0.82 (0.58–1.00)
All Sites Combined (13 providers, 288 clients)	0.87 (0.77–0.97)	0.92 (0.85–0.99)

Exhibit 7: VIA Diagnosis of Reference Standard Observer vs. Providers

Provider Interpretation	Observer Interpretation				
	Other	Negative	Positive	Missing	**Total**
Other	2	0	0	0	**2**
Negative	0	260	0	1	**261**
Positive	0	2	16	0	**18**
Missing	0	3	0	4	**7**
Total	**2**	**265**	**16**	**5**	**288**

Disagreements in Co-Assessments: It is informative to examine the types of disagreements that did occur. **Exhibit 7** above shows the overall level of agreement between providers and the reference standard observer for the VIA diagnosis for all 288 clients. If the judgments of the reference standard observer are regarded as the "truth":

- Of the 265 negative clients (by observer ratings), providers treated two as positive ("over-treatment") and deferred judgment (left the rating blank) on three.
- Of the 16 positive clients (by observer ratings), providers detected/agreed on all.
- Of the five clients with a deferred judgment (by observer ratings, coded as "missing"), the providers deferred judgment on four and considered one to be negative.

Although "over-treatment" may expose the client to the unnecessary procedure of cryotherapy[4], it is arguably more important in the presence of cervical dysplasia that under-treatment does not occur (missing true positives). Thus, it is encouraging that providers detected all of the positive cases identified independently by the observer. The cross-tabulations of VIA diagnoses by facility, as well as by individual provider, are presented in **Appendices 4** and **5**, respectively.

[4] The negative side effects of the cryotherapy procedure are very minimal, with a documented history of low complication rates (Nuovo et al. 2000). Studies have shown that women who had cryotherapy were not at greater risk of negative birth outcomes, such as premature birth or low birth weight (El-Bastawissi et al. 1999).

Results 2. Performance Standards Achievements

The performance standards tool presents all of the steps and sub-steps involved in conducting VIA and cryotherapy, allowing us to make a detailed analysis of providers' strengths and weaknesses in different parts of the procedures. At completion of training, a provider is expected to have a minimum of 85% achievement (percentage out of the 10 criteria achieved) of all of these standards. We used the 85% achievement value as our baseline comparison value.

Performance standards achievements for providers in Ghana were generally very high. **Exhibit 8** presents the performance standards, upon which providers were "graded," for both VIA and cryotherapy. With the exception of some missing values at the criteria level, all providers were observed performing every standard.

Providers correctly achieved every criterion for all standards, except for one provider who incorrectly performed all criteria for the "Preparation for VIA Test" standard in the VIA procedure, and another who did not correctly check the indicator gauge in preparation for the cryotherapy procedure. All providers, however, were well over the 85% achievement level, with the average score being 99% for the VIA procedure and 98% for the cryotherapy procedure.

Exhibit 8: Performance Standards for VIA and Cryotherapy—Ghana

Performance Standards	Criteria
VIA	
Effective counseling skills	▪ Greet the client with respect and kindness ▪ Listen actively to what the woman says ▪ Answer questions directly in a calm and reassuring manner ▪ Help the woman make own decision without suggesting what she should do
Respectfulness to woman's rights at all times	▪ Tell her that the information she provided will not be shared with anyone not directly involved in her treatment without her permission ▪ If woman wants to involve anyone in decision-making, respect her wishes
Assurance of client's privacy at all times	▪ Use a separate area such as an office, closed treatment room, or curtained space ▪ Draw curtains around the treatment area whenever the woman is undressed, or turn the treatment table so that the woman's feet are not facing the doorway or public space ▪ Use drapes or plain cloth sheets to cover the woman's legs and body during examination
Counseling prior to VIA test	▪ Explain how the pelvic examination is done ▪ Explain how the VIA test and cryotherapy prevent cervical cancer ▪ If the woman chooses to have a VIA test, ask her if she has any other questions about the VIA test
Preparation for VIA test	▪ Ask the woman to wash genital area and empty bladder ▪ Wash hands thoroughly with soap and water or alcohol handrub and dry with clean, dry cloth or air dry ▪ Put a new pair of examination gloves on both hands
Pre-inspection for VIA test	▪ Inspect external genitalia and check urethral opening for discharge ▪ Palpate Skene's and Bartholin's glands

Performance Standards	Criteria
VIA *continued*	
Inspection for VIA test	▪ Insert speculum with care and adjust it so that the entire cervix can be seen ▪ Examine the cervix for cervicitis, ectopion, tumors, Nabothian cysts or ulcers
Application of acetic acid	▪ Apply dilute acetic acid using cotton balls ▪ Observe the cervix one minute right after acetic acid application and record any changes ▪ Remove any remaining acetic acid from the cervix and vagina using fresh cotton balls
Post-VIA test infection prevention tasks	▪ Remove gloves by turning inside out ▪ Dispose of gloves by placing in leakproof container or plastic bag ▪ Wash hands thoroughly with soap and water or using alcohol handrub and dry with clean, dry cloth or air dry
Post-VIA counseling (all clients)	▪ Ask the woman to sit up, get down from the examining table and get dressed ▪ Tell the result ▪ Record the VIA result and other findings in the woman's health passport and logbook
Post-test counseling (result specific)	<u>For a negative result:</u> ▪ Discuss with the woman the result of the VIA test and what it means to her reproductive health ▪ Advise the woman to return for repeat test after 5 years ▪ Provide follow-up visit instructions <u>For a positive result:</u> ▪ Discuss with the woman the result of the VIA test and what it means to her reproductive health ▪ Encourage the woman to ask questions and discuss her condition ▪ If the woman is eligible for cryotherapy, ask the woman if she is pregnant ▪ Ask the woman to give her consent for treatment
Documentation	▪ Complete each required element in the VIA and/or cryotherapy record ▪ Document the cervical lesion findings on the cervical map ▪ Document recommended follow up
Cryotherapy	
Detailing information about the treatment options	▪ Explain why the treatment is recommended and describe the procedure ▪ Describe the benefits and effectiveness of cryotherapy ▪ Explain the potential side effects and ensure that the woman understands ▪ Verify that the woman consents to the treatment
Preparation for cryotherapy	▪ Check that CO_2 tank is turned on and the gauge indicator is between 40 and 70 kg/cm^2 ▪ Prepare cryogun by inserting high-level disinfected (HLD) cryotip
Cryotherapy (Step 1)	▪ Insert speculum with care and expose the entire cervix

Performance Standards	Criteria
Cryotherapy *continued*	
Cryotherapy (Step 2)	▪ Check cryogun function by pressing freeze button for 1 second and then defrost button for 1 second ▪ Apply the cryotip to the cervix ▪ Freeze cervix for 3 minutes ▪ After 3 minutes, wait for the cryotip to defrost
Cryotherapy (Step 3)	▪ Wait 5 minutes and repeat the procedure ▪ Close master cylinder valve
Post-cryotherapy infection prevention tasks	▪ Remove gloves by turning inside out ▪ Dispose gloves by placing in leakproof container or plastic bag ▪ Wash hands thoroughly with soap and water or using alcohol handrub
Post-cryotherapy counseling	▪ Check to be sure that the woman is not having excessive cramping ▪ Advise the woman about post-treatment warning signs ▪ Discuss need for abstinence for 4 weeks or the use of condoms when sexual contact cannot be avoided ▪ Provide post-procedure care and follow-up instructions verbally and in writing
Decontamination of instruments	▪ Place instruments in decontamination bucket immediately after use ▪ Leave instruments in decontamination bucket for 10 minutes ▪ Move instruments into bucket of soapy water and scrub ▪ Use appropriate disinfectant to wipe down the main body of the cryogun ▪ Remove and disinfect the cryotip prior to storage
Storage of HLD metal instruments	▪ Immediately store instruments in HLD covered containers

Results 3. Provider Interviews

The results from the provider and supervisor interviews reflected a program that has had limited external support from the central level. All 12 providers interviewed reported that the quality of CECAP services in their facility was assessed or monitored on a regular basis. Most providers who reported use of quality control mechanisms to maintain the quality of CECAP services cited peer review (eight providers), as opposed to review by external personnel (two providers) or immediate supervisors (three providers).

Specific methods of peer review that were mentioned included:

- Informal observation of each other interacting with clients (nine providers said they do this once or twice per month); and
- Co-assessments of VIA testing (nine providers said they do this at least once per year or more).

In addition, providers mentioned that they work together in a team to implement the following performance improvement methods:

- Review of client suggestions/feedback (10 providers said they had done this, including eight who said they do it at least twice a month)
- Review of service statistics reports/registers (10 providers said they do this once a month or more frequently)

- Comparison of the performance of their facility with other facilities/benchmarking (six providers said they do this at least once a year)

It appears that although external supervision was very limited, some supervision by the immediate supervisor did take place. Half of the providers reported being supervised within the last one to two months.

DISCUSSION

This study has demonstrated that providers of cervical cancer prevention services in Ghana were able to maintain an encouragingly high level of quality in both the diagnosis of the cervix and the case management decision, after external support was discontinued. Moreover, this high level of quality was maintained despite the fact that external inputs—such as supervision, refresher trainings and systematized information systems—have not yet been established in Ghana.

One limitation of these data is that the reference standard observers were among the group of people who originally trained the providers. This aspect of the study design was unavoidable, despite the bias it may have caused in the results, because there are so few providers in Ghana qualified to fulfill this role. Another limitation is the small scale of the program. Report findings are true of only three health facilities and 13 providers. If the effort were scaled-up to additional sites, it is not clear whether the level of quality reported here would be sustained. Possibly, stronger professional support and information systems would be needed to maintain a high level of quality in a scaled-up context.

Despite the relatively low level of external support or supervision, Ghanaian providers scored within the overall range of "near perfect" using the Kappa analysis on reliability of repeat measures for diagnoses of the cervix and case management decisions. Furthermore, average performance standards achievement scores were in the 90^{th} percentile for such aspects of service as infection prevention and counseling for both VIA and cryotherapy. It is possible that the sheer volume of clients in Ghana kept providers consistently busy, contributing to the upkeep of skills. Again, in Ghana, between 2000 and 2006, these 13 providers screened over 19,000 women; and at the peak of productivity, individual providers in Ghana were screening over 60 clients per month.

Despite limitations of the study, the high level of quality maintained in provider performance after the withdrawal of external support is notable. These findings should be of interest to various countries, some of them similar to Ghana, which are in the process of adopting or scaling up cervical cancer prevention programs based on the single visit approach using VIA and cyotherapy.

APPENDIX 1. SAMPLE SIZES FOR KAPPA VALUES

This appendix presents a portion of the Sim & Wright (2005) sample size table. **Exhibit 9** shows sample sizes for the 80% or 90% power required to detect Kappa values significantly different from a Kappa of 0 (anywhere from 0.40 to 0.80) given a low positive rate value (we expected a 10% positive rate).

Exhibit 9: Selected Sample Size Estimates from Sim & Wright (2005) for Two-Rater Kappa on a Dichotomous Test in a Low-Prevalence Situation

Expected Proportion of Positive Ratings	Kappa to Detect	No. Needed at 80% Power (Two-Tailed Test)	No. Needed at 90% Power (Two-Tailed Test)
0.10	0.40	50	66
0.10	0.50	32	43
0.10	0.60	22	30
0.10	0.70	17	22
0.10	0.80	13	17
0.10	0.90	10	13

APPENDIX 2. FURTHER INFORMATION ON CODING FOR KAPPA CALCULATION

This appendix further explains how the coding of cervical diagnoses was done for the Kappa calculation, in particular the coding of "other" values.

Although the forms contained three options for both the VIA test result and the case management decision (VIA diagnosis options: negative, positive or suspect cancer; case management options: counsel to return after five years [for negative result], cryotherapy [for positive result] or referral [if cancer was suspected]), both providers and observers added two more options, in effect, for each decision. In some cases, they left the decision blank; in other cases, they wrote in a different comment or decision instead of choosing one of the three given options. For example, one provider wrote "unreadable" for the VIA result, and for case management wrote "to see specialist in two weeks."

Such write-ins were treated as a fourth option ("other") and included as such in the analyses. Decisions left blank were coded as a fifth option ("missing"), and also included in the analyses. It should be noted that these "missing" entrees essentially indicated a decision to defer VIA testing because of cervical conditions that would interfere with the test (e.g., cervicitis, cysts). Both providers and observers indicated these conditions in the cervical map, and wrote-in alternative case management decisions such as "perform VIA test in two weeks following referral for cyst," so that it would be clear why they had left the VIA interpretation blank.

In cases where it appeared that the rater simply forgot to code the VIA result (e.g., the VIA result was missing, but the cervical map showed a normal image and the management decision was "counsel to return after five years"), the VIA decision was deduced and entered. However, if the rater made confusing codings (e.g., blank VIA interpretation accompanied by a clear cervical map and a decision to perform cryotherapy), the VIA interpretation was not recoded to "negative" or "positive" but rather to "missing," and was counted as a disagreement if different from the observer's coding. Thus, the rule for missing data points required that judgment could only be inferred if two out of three of the information sources on the form (VIA interpretation, cervical map drawing and case management decision) showed consistency.

There were only nine out of 288 cases in which inference of a coding had to be made based on two of three pieces of information. Of these nine, two were VIA judgments and seven were case management judgments (the rater coded the VIA and drew the cervical map, but left the management decision blank).

APPENDIX 3. CONFIDENCE INTERVALS AND LOW PREVALENCE OF CERVICAL PRECANCER IN KAPPA CALCULATION

This appendix provides information on the confidence intervals associated with the Kappa statistic. **Exhibit 10** shows that the majority of providers are in agreement with the reference standard observers at a level significantly above chance (seven of the nine CIs exclude 0 for VIA, and eight of nine CIs exclude 0 for the case management decision).

Exhibit 10: Kappas for VIA and Case Management Decisions by Specific Providers (vs. Observer)

Health Facility	Provider	Clients	Kappa: VIA (95% CI)	Kappa: Case Mgmt. (95% CI)
Ridge Hospital	A	25	0.78 (0.38–1.00)	1.00 (1.00–1.00)
	B	24	1.00 (1.00–1.00)	1.00 (1.00–1.00)
	C	24	0.79 (0.38–1.00)	0.79 (0.38–1.00)
	D	25	1.00 (1.00–1.00)	1.00 (1.00–1.00)
	E	25	1.00 (1.00–1.00)	1.00 (1.00–1.00)
	F	25	0 (0–0)	0.47 (- 0.12–1.00)
Amasaman Health Centre	G	25	1.00 (1.00–1.00)	1.00 (1.00–1.00)
	H	25	1.00 (1.00–1.00)	1.00 (1.00–1.00)
	I	25	0.47 (- 0.14–1.00)	1.00 (1.00–1.00)

As can be seen, when the Kappa is not 0 (no agreement above chance) or 1.0 (perfect chance-corrected agreement), the confidence intervals are quite wide. For example, even though Provider C has a VIA Kappa of 0.79 ("substantial" agreement by the Landis & Koch [1977] standards), the CI indicates that the actual agreement could be as low as 0.38 ("fair" by Landis & Koch, 1977) or as high as 1.0 ("perfect").

Similarly, the wide range of CIs must be kept in mind when comparing Kappas across providers. The VIA Kappa of 0.47 for Provider I would seem to be very different from the 0.79 of Provider C, but examination of the CIs for each statistic indicates that either of these providers could have a Kappa as high as 1.0. The overlap of their CIs indicates that they could in fact have the same Kappa.

Sim & Wright (2005) point out that very low or very high prevalence of a condition under study has a strong impact on Kappa. This is certainly a problem to be acknowledged in the present study, when examining individual providers. Although we do not have an independent population-based study of the prevalence of cervical lesions in Ghana, our estimate from the overall sample is approximately 6%. For the situation in which a dichotomous test is being evaluated by two raters, Sim & Wright (2005) denote the prevalence index as the absolute difference between the cells of agreement (a & d) divided by the total number of subjects (*N*), as follows:

		Rater 2	
		VIA+	VIA-
Rater 1	VIA+	a	b
	VIA -	c	d

Prevalence index = | a – d | / *N*

Although our test has more than two possible results, we can ignore the third result ("missing") to make an illustration of the prevalence index, using the data in **Exhibit 11** for Provider I. Excluding the single client rated "missing," we have 24 clients, with 22 jointly coded negative, one jointly coded positive and one discordantly rated. The prevalence index here would be |22 - 1| /24 = 0.88, which is quite high because of the low prevalence of VIA-positive results. The proportion of observed agreement among the 24 cases would be 23/24 = 0.96, and the proportion of chance agreement would be 0.88, with a resulting Kappa of 0.65.

Exhibit 11: VIA Agreement for Provider I vs. Observer*

		OBSERVER INTERPRETATION			
		Negative	**Positive**	**Missing**	**Total**
Provider Interpretation	Negative	22	0	1	**23**
	Positive	1	1	0	**2**
	Missing	0	0	0	**0**
	Total	**23**	**1**	**1**	**25**

* Kappa = 0.47 [- 0.14–1.00]

If the prevalence of VIA test-positive cases were higher, the prevalence index would approach 0. To illustrate this point, suppose test-positive cases were approximately equal to test-negative cases, so that instead of 22 negative/negative cases shown, we had 12, and instead of one positive/positive case we had 11 (still for a total of 23 cases in agreement). The prevalence index would then be |12 - 11| /24 = 0.04. The proportion of observed agreement among the 24 cases would still be 23/24 = 0.96, but the proportion of chance agreement would be 0.50, yielding a Kappa of 0.92. Thus, in low-prevalence versus balanced-prevalence situations, we have the same proportion of observed agreement (0.96), but very different proportions of chance agreement, making for very different Kappas. Likewise, the Kappa would be much higher than 0.47 if the 23 clients on whom the provider and observer agreed were distributed evenly across the diagonal (e.g., eight negative/negative, eight positive/positive, and seven missing/missing).

APPENDIX 4. VIA TESTING JUDGMENTS OF OBSERVER VERSUS PROVIDERS BY FACILITY

Exhibits 12 through **14** present the VIA diagnoses of the providers compared to those of the reference standard observer, by facility.

Exhibit 12: Ridge Hospital: VIA Diagnoses of Observer vs. Providers

		Observer Interpretation				
		Other	**Negative**	**Positive**	**Missing**	**Total**
Provider Interpretation	Other	2	0	0	0	**2**
	Negative	0	132	0	0	**132**
	Positive	0	0	10	0	**10**
	Missing	0	3	0	1	**4**
	Total	**2**	**135**	**10**	**1**	**148**

Exhibit 13: Amasaman Health Centre: VIA Diagnoses of Observer vs. Providers

		Observer Interpretation			
		Negative	**Positive**	**Missing**	**Total**
Provider Interpretation	Negative	68	0	1	**69**
	Positive	1	3	0	**4**
	Missing	0	0	2	**2**
	Total	**69**	**3**	**3**	**75**

Exhibit 14: Kumasi South Hospital: VIA Diagnoses of Observer vs. Providers

		Observer Interpretation			
		Negative	**Positive**	**Missing**	**Total**
Provider Interpretation	Negative	60	0	0	**60**
	Positive	1	3	0	**4**
	Missing	0	0	1	**1**
	Total	**61**	**3**	**1**	**65**

APPENDIX 5. INDIVIDUAL PROVIDER VIA INTERPRETATIONS

This appendix presents the VIA diagnoses of the providers compared to those of the reference standard observer, by individual provider.

In planning the reliability exercise, we considered the number of clients who would need to be seen by each provider/observer pair in order to have confidence in the stability of the resulting Kappa statistic. For the calculation of statistical power and sample size for Kappa, we took some guidance from a recently published sample size table (Sim & Wright 2005) for Kappas calculated for two raters making a dichotomous decision (although it should be noted that our situation involves at least a trichotomous decision when the VIA choices are negative versus positive versus suspected cancer, and more when we add "other" and "missing" as options). **Appendix 1** contains information on the sample sizes needed to detect Kappa values in a relevant range for our analysis.

We opted for a goal of collecting 25 observations per provider (with expected 10% prevalence this would yield approximately two to three positive clients per provider). We were able to see approximately 25 clients per provider at both Ridge Hospital and Amasaman Health Centre, but the client flow was insufficient at Kumasi South Hospital, with approximately 15 clients per provider. Given this number of clients, we were able to make the Kappa estimates for each facility and overall, but not for individual provider Kappas at Kumasi South Hospital.

Exhibit 10 (page 17, Appendix 1) describes the provider-specific Kappas observed at Ridge and Amasaman. From these, we can conclude that the majority of providers are in agreement with the reference standard observer at a level significantly above chance (seven of the nine CIs exclude 0 for VIA, and eight of the nine CIs exclude 0 for the case management decision). As can be seen, when the Kappa is not 0 (no agreement above chance) or 1.0 (perfect chance-corrected agreement), the confidence intervals are quite wide.

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