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International Journal of Gynecology and Obstetrics 124 (2014) 12–18

Contents lists available at ScienceDirect

International Journal of Gynecology and Obstetrics

journal homepage: www.elsevier.com/locate/ijgo

CLINICAL ARTICLE

Successes and challenges of establishing a cervical cancer screening and treatment program in western Kenya ☆

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ARTICLE INFO

Article history:
Received 29 January 2013
Received in revised form 22 June 2013
Accepted 17 September 2013

Keywords:
Cervical cancer screening
Loss to follow-up
Sub-Saharan Africa
Visual inspection with acetic acid

ABSTRACT

Objective: To describe the challenges and successes of integrating a public-sector cervical screening program into a large HIV care system in western Kenya. *Methods:* The present study was a programmatic description and a retrospective chart review of data collected from a cervical screening program based on visual inspection with acetic acid (VIA) between June 2009 and October 2011. *Results:* In total, 6787 women were screened: 1331 (19.6%) were VIA-positive, of whom 949 (71.3%) had HIV. Overall, 206 women underwent cryotherapy, 754 colposcopy, 143 loop electrical excision procedure (LEEP), and 27 hysterectomy. Among the colposcopy-guided biopsies, 27.9% had severe dysplasia and 10.9% had invasive cancer. There were 68 cases of cancer, equating to approximately 414 per 100 000 women per year. Despite aggressive strategies, the overall loss to follow-up was 31.5%: 27.9% were lost after a positive VIA screen, 49.3% between biopsy and LEEP, and 59.6% between biopsy and hysterectomy/chemotherapy. *Conclusion:* The established infrastructure of an HIV treatment program was successfully used to build capacity for cervical screening in a low-resource setting. By using task-shifting and evidence-based, low-cost approaches, population-based cervical screening in a rural African clinical network was found to feasible; however, loss to follow-up and poor pathology infrastructure remain important obstacles.

1. Introduction

Cervical cancer is one of many epidemics that disproportionately affect low-income countries. The WHO estimates that there are 500 000 new cases of, and 275 000 deaths from, cervical cancer each year worldwide. Approximately 90% of cases and 95% of deaths from cervical cancer occur in low-income countries [1,2]. In many such regions, cervical cancer kills more women compared with any other cancer [1]. Given the limited screening and diagnostic capabilities in these countries, most women present with late-stage, fatal disease [1]. With the ongoing population growth of low-income countries, deaths due to cervical cancer are projected to rise by almost 25% in the next 10 years [1]. In Kenya, the crude incidence of cervical cancer is estimated to be at least 16 cases per 100 000 women per year, although this is probably an underestimate [3]. Thus, the need for screening for cervical cancer in Kenya has become an important health priority [4].

Many of the countries with the highest burden of cervical cancer also face an unrelenting HIV epidemic; for example, the prevalence of HIV among women aged 15–49 years in Kenya was 8.0% in 2009 [5]. HIV infection confers a greater risk for developing cervical dysplasia and cancer. The incidence of cervical intra-epithelial neoplasia (CIN) is 4 to 5 times higher among HIV-infected women than among their uninfected counterparts [6,7]. Women with low CD4 cell counts have the highest prevalence of human papillomavirus (HPV) infection and more commonly harbor high-risk oncogenic HPV subtypes that are associated with severe dysplasia and cervical cancer [8–11]. The natural progression of cervical dysplasia is accelerated, because the average interval between diagnosis of CIN and invasive disease may be shortened from 15.7 to 3.2 years [12]. Until recently, access to anti-retroviral therapy was very limited for HIV-infected women in low-income countries. As

☆ Presented as a poster at the 14th Biennial Meeting of the International Gynecologic Cancer Society; October 13–16, 2012; Vancouver, Canada.

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0020-7292/$ – see front matter
http://dx.doi.org/10.1016/j.ijgo.2013.06.035

highly active antiretroviral therapy (HAART) has become more accessible, however, HIV-infected women in low-resource regions are living longer and are increasingly vulnerable to death from chronic diseases including cervical cancer. In contrast to other AIDS-defining malignancies, the incidence of cervical cancer in HIV-infected women has not been decreased by the introduction of HAART [13,14].

Screening for cervical cancer in low-income countries has many inherent challenges, including a lack of public awareness, a lack of screening and diagnostic modalities, poor health infrastructure, understaffing, a cultural aversion to discussing sexual function, poor medical records, and high losses to follow-up [1]. The many logistic prerequisites for a successful Pap-smear based program (preparation of high-quality smears, well-trained and experienced cytologists, logistics to transport specimens and results, and substantial health system strengthening to follow patients longitudinally) pose major challenges to implementation in low-income countries [15,16]. In response to this challenge, more cost-effective methods of cervical cancer screening have been developed and tested [15]. The least expensive of these is visual inspection with acetic acid (VIA), which has been shown to decrease incidence and mortality in low-resource settings, and has been validated as a screening method among women infected with HIV [16,17].

VIA has been embraced as an easily implemented, low-tech screening method; however, there remain many barriers to the development of a comprehensive cervical cancer screening and treatment program regardless of the modality of screening test chosen. Most importantly, such programs must be measurable and sustainable in the long term. The 2011 Wakley Prize Essay eloquently argues that short-term, disease-specific interventions, frequently spearheaded by international health organizations, can be a real source of harm to the comprehensive district health system in place in most low-resource countries [18]. Temporary mass screenings for cancers, such as breast and cervical cancer, occur intermittently in Kenya and are a well-intentioned effort; however, reduction in mortality from cervical cancer depends on early detection and early treatment of precancerous and cancerous disease [1]. Thus, in the absence of comprehensive services to treat precancerous and cancerous disease, targeted mass screenings are unlikely to affect cervical cancer morbidity and mortality.

The impetus to start a comprehensive cervical cancer program in Kenya arose in response to the high morbidity and mortality from cervical cancer observed in HIV clinics and referral hospitals supported by The Academic Model Providing Access to Healthcare (AMPATH) in western Kenya. AMPATH is a collaboration among 9 North American universities and medical centers that is led by the Indiana University School of Medicine, Moi University School of Medicine (MUSOM), Moi Teaching and Referral Hospital (MTRH), and Kenyan Ministries of Health (MOH) [19]. AMPATH started in 1990 as an HIV/AIDS prevention and treatment program. Collaboratively, AMPATH and MUSOM established HIV treatment clinics at existing MOH district clinics and have subsequently enrolled approximately 150 000 individuals infected with HIV at 65 rural sites in western Kenya. AMPATH has since evolved and expanded its focus to include primary care and chronic disease management, with programs addressing tuberculosis, hypertension, diabetes, oncology, maternal mortality, family planning, food insecurity, orphans and vulnerable children, and income generation.

In 2009, a pilot study funded by the Fogarty International Center (NIH) was conducted to evaluate the test characteristics of VIA and the feasibility and acceptability of cervical cancer screening among women infected with HIV in western Kenya [16]. The study validated VIA as an acceptable method of screening for HIV-infected Kenyan women, and confirmed the high prevalence of abnormal screens in that cohort. In addition, the pilot facilitated the development of a functional clinic model and a core of well-trained MOH nurses and doctors who could provide clinical care and serve as regional trainers and specialists.

After successful completion of the pilot study, the cervical cancer screening program was extended. Utilizing the clinical and human resources developed from the pilot study [16], in addition to the organizational infrastructure and supply chain of AMPATH, the program was expanded to 4 regional health facilities over the course of 2 years, serving an estimated catchment population of approximately 1 million. In this context, the aim of the present study was to explore the challenges and successes of a public sector cervical cancer screening program in western Kenya.

2. Materials and methods

In the present retrospective, descriptive study, data were analyzed from women who underwent cervical cancer screening by VIA between June 1, 2009, and October 31, 2011. The cervical cancer screening program was rolled out as a clinical program and hence ethical approval was required for retrospective analysis of de-identified data. Ethical approval was obtained from the Institutional Research and Ethics Committee at MUSOM, Eldoret, Kenya, and Indiana University's Institutional Review Board in Indianapolis, IN, USA.

After the pilot study [16], the screening program was expanded to 4 regional health facilities. To increase screening uptake in these communities, an Information–Education Campaign was implemented by means of health talks, T-shirts, and print media to raise awareness about the availability and necessity of screening. For equity reasons, screening was offered regardless of HIV status. Patients were actively recruited for screening from both AMPATH-supported HIV clinics and maternal–child health clinics at the 4 facilities. The target age range for screening was 21–65 years; however, HIV-infected patients of any age were accepted for screening owing to their increased risk of cervical dysplasia and progression to cancer.

To staff these 4 facilities adequately, significant training, mentorship, and capacity building was required. The program used a training curriculum adapted from the WHO's International Agency for Research on Cancer (IARC), and key nurses underwent additional training in cryotherapy and cervicography in Lusaka, at the Centre for Infectious Disease Research in Zambia [20–22]. These key nurses then trained (using IARC-based materials) and mentored other local MOH nurses who staffed the cervical cancer screening services in their clinics. A core group of local gynecologists from MUSOM underwent specialized training and continuous mentorship from visiting North American gynecologists to become skilled at colposcopy, biopsy, and loop electrical excision procedure (LEEP).

The AMPATH–MUSOM collaboration provided the regional logistic support, supply chain management, and screening rooms. Most screening supplies were procured domestically in accordance with MOH procurement policies; however, some specialized supplies could not be sourced nationally and required importation.

Box 1
Cryotherapy eligibility criteria.

1. Lesion is associated with the squamocolumnar junction.
2. Lesion covers 75% or less of the squamocolumnar junction.
3. Lesion is seen in its entirety and does not disappear into endocervical canal.
4. There are no abnormal blood vessels.
5. There is no cervical lesion (polyp) or anatomic defect (scarring or fibrosis) that prevents flush contact between cervix and cryoprobe.
6. There is no clinical evidence of cancer (ulcerations, heaped edges, excessive bleeding from friable tissue).
7. Patient is not pregnant.

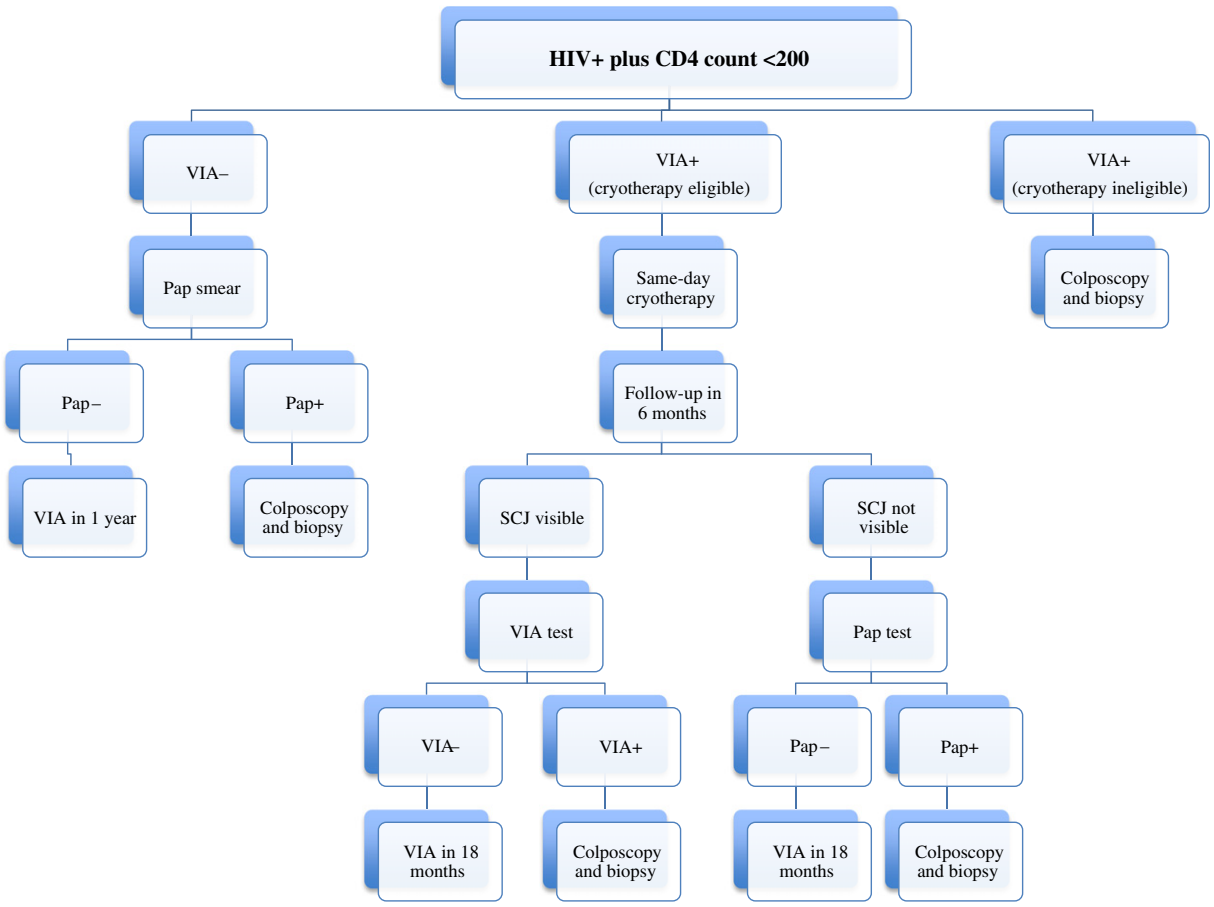

Fig. 1. Screening algorithm used for HIV-positive women with a CD4 count of less than 200. Abbreviations: SCJ, squamocolumnar junction; VIA, visual inspection with acetic acid (VIA).

Expansion to the 4 new facilities necessitated the development of standardized screening and treatment algorithms to ensure the same quality of care at all locations (Box 1 and Figs. 1–3). HIV-infected women with a CD4 count of 200 or less were screened yearly, whereas HIV-uninfected women and HIV-infected women with a CD4 count of more than 200 were screened every 3 years. The program was based on a "see-and-treat" model, whereby nurses could independently screen with VIA and treat with cryotherapy in a single encounter for patients meeting IARC criteria [20]. For those patients who were ineligible for cryotherapy as per IARC guidelines, a mobile colposcopy service was developed with trained local gynecologists, who rotated through each site offering colposcopy and biopsy on a monthly basis. Colposcopy-guided biopsies were collected at all sites and were transported to the referral hospital for evaluation by local pathologists. Results were returned to regional clinics within 1–2 months and reviewed by a gynecologist. Cryotherapy-ineligible patients with biopsy-proven dysplasia were sent to the referral hospital for outpatient LEEP.

Most patients in the catchment population had access to a cellular telephone within their household. To address potential losses to follow-up along the continuum of care, an appointment system was implemented and the cell phone network in the region was used to provide reminder calls and text messages prior to scheduled appointments. Lay person clinic assistants were hired to help nurses with filing medical records, recording upcoming appointments, and calling patients in advance to remind them of upcoming follow-up appointments.

Because the program would identify patients with both pre-invasive and invasive disease, a training and mentorship program in medical and surgical gynecologic oncology was developed concurrently. As described by Elit et al. [23], this program trained 2 Kenyan gynecologists to perform radical hysterectomy, administer chemotherapy, and provide palliative care. Patients with early stage cancer were treated by either simple or radical hysterectomy. Patients with advanced cervical cancer were offered chemotherapy and referral for radiation or palliation, depending on the extent of the disease.

Data were initially recorded in logbooks and then converted to an Excel database (Microsoft, Redmond, WA, USA). Only data on the VIA-positive patients were included in the database. Simple means and percentages were calculated via Microsoft Excel 2004.

3. Results

During the study period, 6787 women were screened. The average age at screening was 38 years (range 17–75 years), and 1331 (19.6%) women had a positive VIA screen. Among those with VIA-positive screens, 949 (71.3%) were infected with HIV. A total of 206 cryotherapy procedures, 754 colposcopies, 114 LEEP procedures, and 27 hysterectomies were performed. There were 68 invasive cancers among the 6787 women screened, equating to an incidence of 414 per 100 000 women per year (Table 1).

Fig. 4 shows the cumulative number of screens across all sites. The enrollment of women increased as new sites opened, existing sites became more efficient, and community awareness increased.

By treating CIN 2/3 using LEEP or cryotherapy, 349 cases that may have progressed to cancer if left untreated were averted. Cryotherapy procedures increased as the nitrous oxide supply and cryotherapy devices became operational. Simultaneously, colposcopy rates began to plateau as cryotherapy utilization increased (Fig. 5).

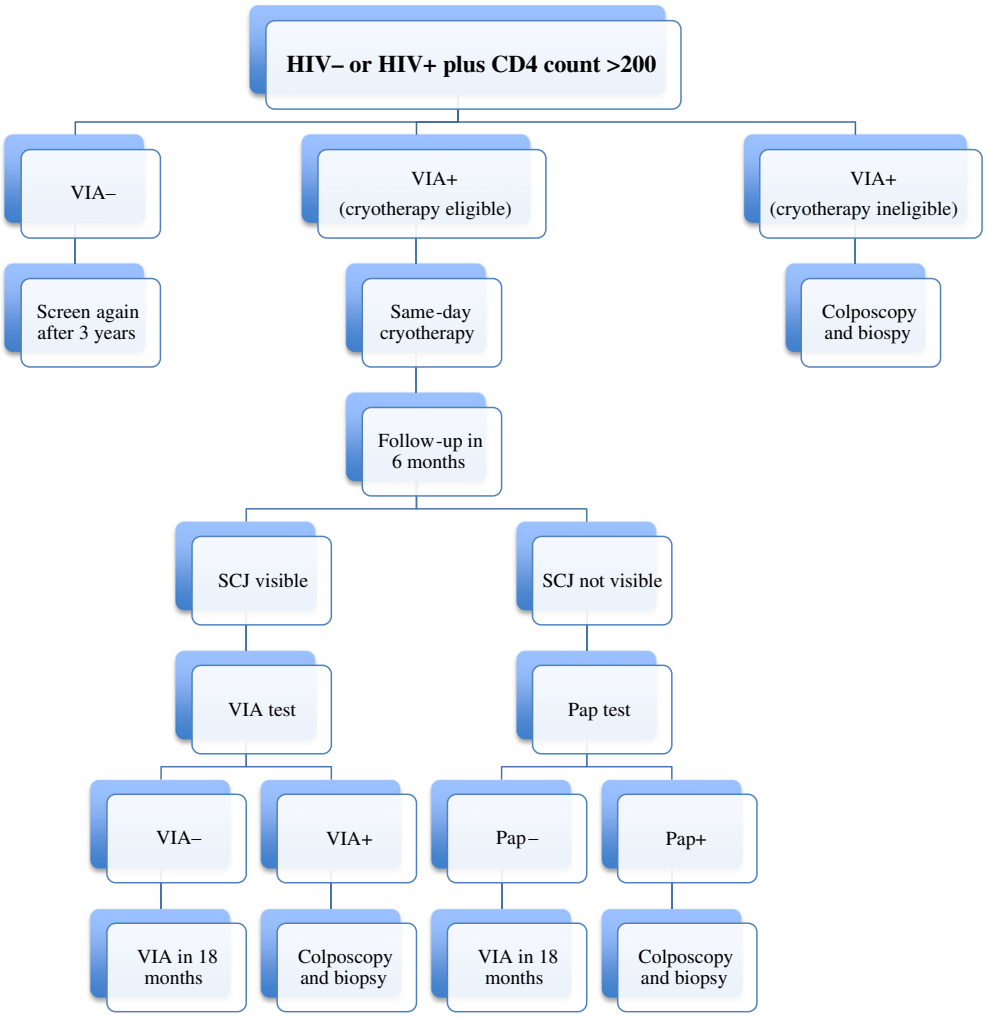

Fig. 2. Screening algorithm used for HIV-negative or HIV-positive women with a CD4 count of higher than 200. Abbreviations: SCJ, squamocolumnar junction; VIA, visual inspection with acetic acid (VIA).

Among patients who underwent a colposcopy-guided biopsy, 27.9% had severe dysplasia and 10.9% had invasive cancer. Overall, 38.8% had severe dysplasia or worse. Table 2 lists the distribution of pathology results for colposcopy-guided biopsies; 19.5% were still pending at the end of the evaluation period.

Despite the use of mobile phone-based appointment reminders, there was a significant loss to follow-up at each step in the continuum of care. Loss to follow-up was defined as not returning for appropriate treatment after receiving a phone call reminder. The overall loss to follow-up rate was 31.5% (491/1558). There was an increasing loss to follow-up rate as the treatment became more invasive. There was a 27.9% loss to follow-up between VIA-positive (cryotherapy-ineligible) and colposcopic biopsy, a 49.3% loss between colposcopy and LEEP, and a 59.6% loss between colposcopy and hysterectomy or chemotherapy. Table 3 shows the median follow-up time at each point of the treatment cascade, and Fig. 6 depicts the rates of follow-up at each point of the treatment cascade.

4. Discussion

The results from the first 2 years highlight the successes of AMPATH's public sector and rural clinic-based cervical cancer screening program. In a short period of time, the program has screened, diagnosed, and treated a large number of women including many infected with HIV who are vulnerable to the development of cervical cancer. Some of the programmatic successes, however, cannot be directly tabulated from the data.

For example, the program has successfully utilized routine MOH services using local nursing and medical staff, expanded its locations, trained numerous MOH nurses, provided logistic and supply chain support, increased community awareness, and improved regional expertise in cervical cancer screening and treatment.

The results also highlight the many challenges of the program. The biggest challenge—and one of the biggest challenges in cervical cancer screening worldwide—is loss to follow-up. In the study population, approximately one-third of patients who needed treatment for known disease were not seen again. The present study is one of few published studies to record rates of loss to follow-up during each stage of cervical cancer screening in Sub-Saharan Africa. For comparison, cervical screening programs in North America have demonstrated a loss to follow-up rate of up to 26% [24]. The high loss to follow-up rate observed in the present study is probably multifactorial; however, the data demonstrate that see-and-treat-based programs are still faced with patients who require longitudinal care and thus follow-up is likely to remain an issue.

Despite considerable efforts to reduce loss to follow-up by using appointment cards, registers, and cellphone reminders, there remain barriers to follow-up that qualitative research might further illuminate. First, among the women who shared a single phone with their whole

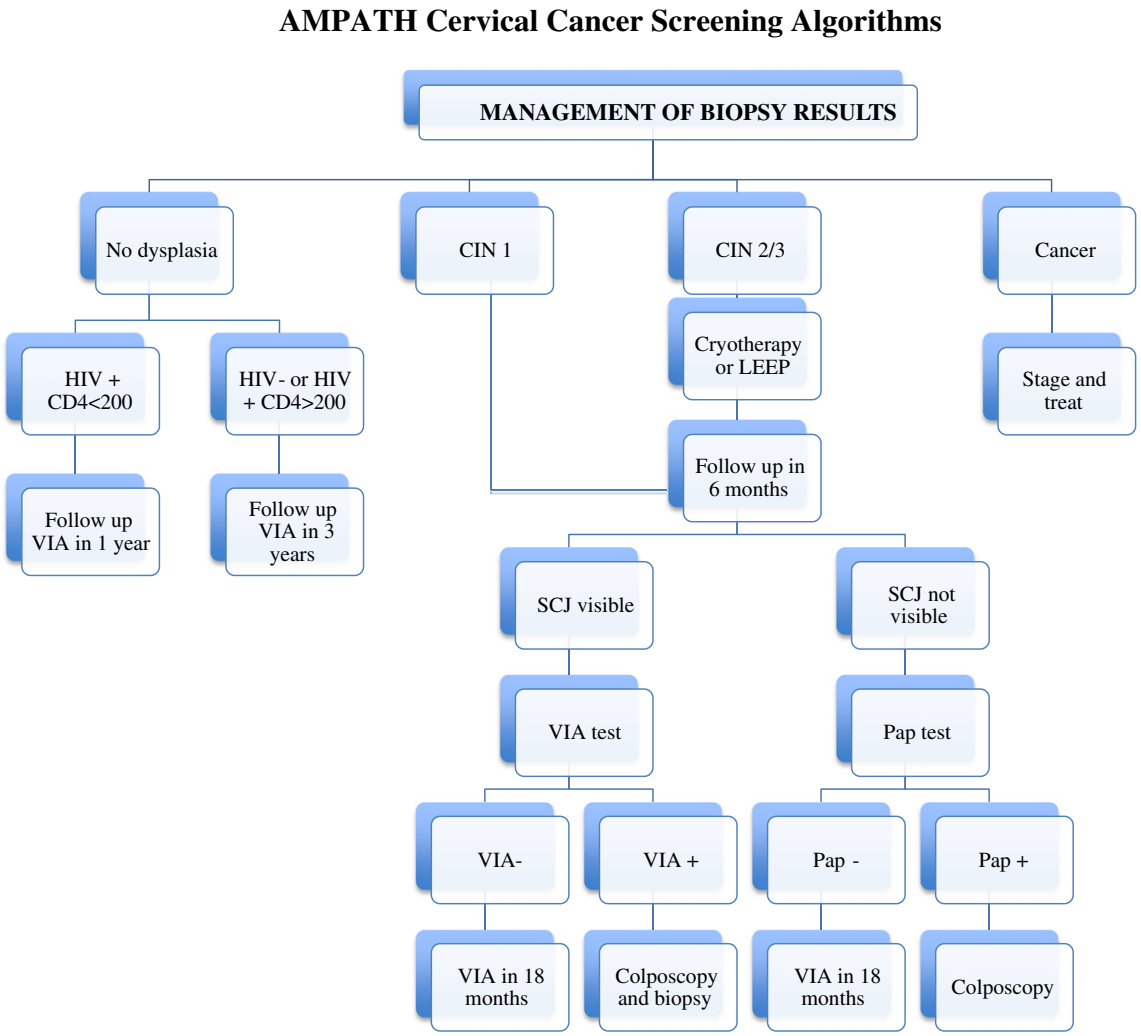

Fig. 3. Algorithm for management of biopsy results. Abbreviations: CIN, cervical intra-epithelial neoplasia; LEEP, loop electrical excision procedure; SCJ, squamocolumnar junction; VIA, visual inspection with acetic acid (VIA).

family, communication was intermittent. Second, despite free services for patients who could not afford treatment, the commute to the referral hospital was costly and lengthy, potentially posing a significant barrier to follow-up. Last, a cultural aversion to diseases of the reproductive organs might discourage patients from seeking treatment for an essentially asymptomatic condition. Future initiatives to reduce the loss to

Table 1
Summary of procedures among the study women.

Procedure	Number (%) of women (n = 6787)
Positive VIA screen	1331 (19.6)
HIV-infected positive VIA screen	949 (71.3)
Cryotherapy	206 (NA)[a]
Colposcopy	754 (NA)[b]
Cervical biopsy	600 (79.6)
LEEP	143 (NA)[c]
Hysterectomy for cancer (simple or radical)	27 (39.7)
Total no. of cervical carcinomas detected	68

Abbreviations: LEEP, loop electrical excision procedure; NA, not available; VIA, visual inspection with acetic acid.

[a] Percentage of women eligible for cryotherapy was not calculable because cryotherapy was not available before April 14, 2011.

[b] Percentage of women eligible for colposcopy was not calculable because criteria for colposcopy changed after the "see and treat" strategy with cryotherapy started.

[c] Percentage of women eligible for LEEP was not calculable because some women with CIN 2/3 underwent cryotherapy after review by consultant.

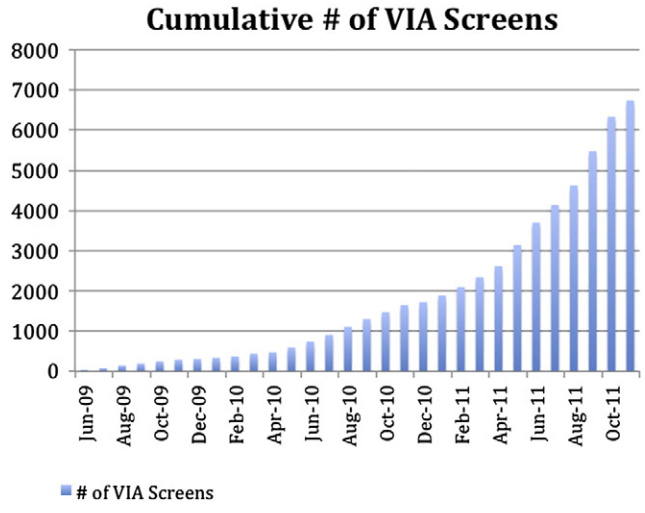

Fig. 4. Cumulative number of VIA screens during the study period.

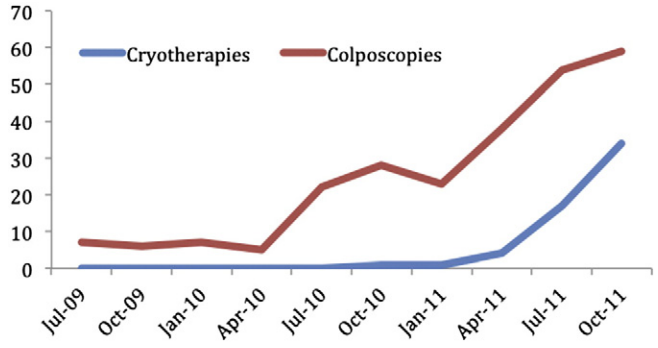

Fig. 5. Monthly number of cryotherapies and colposcopies during the study period.

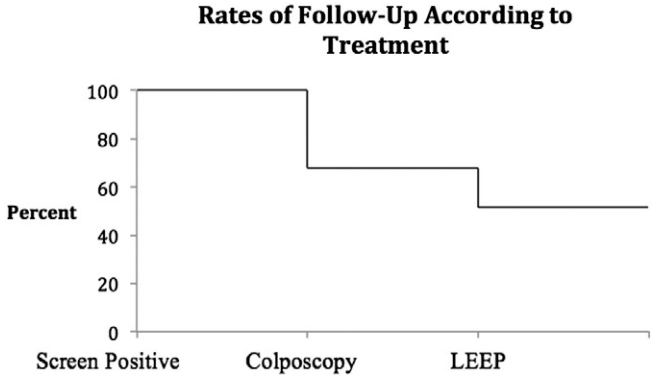

Fig. 6. Percentage of patient follow-up according to treatment.

follow-up rates include evaluating whether eliminating cervical biopsy and performing "see and treat" with LEEP is safe, feasible, and acceptable to the present patient population.

The data highlight another considerable challenge: namely, with increasing screening there is an increasing specimen volume that requires interpretation by skilled histopathologists. In Kenya, as in other Sub-Saharan African countries, there is a shortage of pathologists [25]. From the present data, nearly 20% of histopathology results were still pending at the time of analysis and the median time between biopsy and LEEP was 49 days. Long turnaround times for specimen interpretation result in delays in care and may contribute to the high loss to follow-up.

There are several other important challenges that are not easily demonstrated by the data. One issue that is common across public health programs, including the present program, is staff fatigue. MOH health centers are chronically understaffed and nurses have multiple competing responsibilities including outpatient clinics, prenatal care, and family planning, in addition to cervical screening. This made it difficult to convince nurses in existing facilities to be trained and devote significant time to cervical screening and cryotherapy. A second and related challenge is the relative lack of skilled colposcopy and LEEP providers. Successful expansion to additional rural sites was mediated by the ability to maintain frequent colposcopy clinics at all sites for patients who were ineligible for cryotherapy.

Lastly, supply chain management remains a consistent challenge in the present program. Many cervical cancer screening supplies, including cryotherapy probes, biopsy forceps, ferric sub-sulfate, and silver nitrite, cannot be procured locally or even nationally; instead, they are purchased abroad and imported. This can create significant delays in the delivery of essential supplies, and eventually can lead to long waiting times for treatment and result in deterioration in the quality of patient care. In addition, for some durable equipment such as cryotherapy devices, technical specifications differ between countries, rendering the implementation and maintenance of equipment challenging.

The main limitation of the present descriptive study is the lack of longitudinal data to determine whether the screening and treatment algorithms are effective, especially for patients infected with HIV who received cryotherapy. However, a study is currently underway to evaluate the cure rates and the best modality to follow HIV-infected patients who have undergone cryotherapy or LEEP in the cervical cancer screening program. A second limitation of the study is that the data set did not collect information on VIA-negative patients.

Although VIA represents a low-cost alternative to cytology screening and cryotherapy can be used as a treatment alternative for some patients, substantial logistic challenges remain in "see-and-treat"-based programmes. VIA and cryotherapy alone cannot solve the cervical cancer screening problem. Significant capacity building and health system strengthening will be required to implement any cervical cancer screening program that aims to address the full continuum of disease.

Table 2
Distribution of disease among patients who underwent colposcopic biopsy (n = 600).

Histology	Total (percentage)
No epithelial abnormality	169 (28.2)
CIN 1	65 (10.8)
CIN 2/3 or CIS	167 (27.9)
Microinvasive cancer	13 (2.2)
Invasive cancer	52 (8.7)
Results pending	117 (19.5)
Insufficient	17 (2.8)

Abbreviations: CIN, cervical intra-epithelial neoplasia; CIS, carcinoma in situ.

Table 3
Follow-up interval among the study patients.

Follow-up interval	Median no. of days	Interquartile range (days)
Between VIA-positive (cryotherapy-ineligible patients) and colposcopic biopsy	17	25
Between colposcopic biopsy and LEEP (CIN 2/3 patients only)	49	41
Between colposcopic biopsy and hysterectomy/chemotherapy (CIS, micro-ICC, ICC patients)	52	92

Abbreviations: CIN, cervical intra-epithelial neoplasia; CIS, carcinoma in situ; ICC, invasive cervical cancer; LEEP, loop electrical excision procedure; VIA, visual inspection with acetic acid.

Acknowledgments

The AMPATH Cervical Cancer Screening Program is funded in part by the Pfizer Charitable Foundation.

Conflict of interest

The authors have no conflicts of interest.

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