

Cost Effectiveness of Cervical Cancer Screening Tests in Kenya

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1. Study Background

1.1 Cervical Cancer Burden in Kenya

Cervical cancer is the most prevalent cancer in Sub-Saharan Africa (SSA). With adequate screening and treatment, it is largely preventable. In Kenya, it constitutes 12% of all cancer cases, yet it is the primary cause of cancer-related fatalities¹. The heightened HIV prevalence (6.6%) among Kenyan women amplifies the cervical cancer incidence. With a population of 16.8 million women aged 15 years and above, Kenya faces a significant risk of increased cervical cancer cases. Current estimates indicate that every year 5,236 women are diagnosed with cervical cancer and 3,211 die from the disease².

Burden of cervical cancer	Incidence	Mortality	
Annual number of new cases/ deaths	5,236	3,211	
Crude rate	19.4	11.9	
Age standardized rate	31.3	20.6	
Cumulative risk 0-74 years (%)	3.6	2.5	
Ranking of cervical cancer (all years)	2 nd	1 st	
Ranking of cervical cancer (15-44 years)	2 nd	2 nd	

Table 1: Burden of cervical cancer in Kenya⁽²⁾

1.2 The Status of HPV Vaccination

Due to limited access to screening and treatment, the cervical cancer incidence rate is more than 5 times higher in Kenya compared to High Income Countries (HICs)³. Inequitable access to vaccines against human papillomavirus (HPV) infection is poised to worsen cervical cancer disparities in the future. Cervical cancer stands as the predominant HPV-related disease, with approximately 99.7% of cases attributed to persistent genital high-risk HPV infection⁴. An estimated 9.1% of women in the general population harbor cervical HPV-16/18 infection at any given time, and HPVs 16 or 18 contribute to 63.1% of invasive cervical cancers². Around 70% of cervical cancer cases in Africa could potentially be prevented through HPV vaccination⁵. Optimal vaccination times are during early adolescence before sexual debut and potential HPV exposure. Kenya has introduced HPV vaccination for 10-year-old girls, yet uptake remains suboptimal, with only 33% receiving the first dose in 2020 and approximately 16% returning for the second dose. While COVID-19-related disruptions to immunization programs contributed to low coverage, misinformation and low demand also play significant roles⁶.

1.3 The Status of Cervical Cancer Screening

Cervical cancer screening tests, include conventional cytology (PAP smear), liquid-based cytology (LBC), HPV testing, and visual inspection with acetic acid (VIA), which can detect cervical precancerous lesions in asymptomatic women⁷. For individuals aged 25-65 years, HPV testing is recommended every 5 years, cervical cytology alone every 3 years, or co-testing with a combination of cytology and HPV testing every 5 years⁸. The HPV test detects the presence of the human papillomavirus, which can cause cell changes on the cervix, while Pap smear identifies precancerous cell changes that could develop into cervical cancer if left untreated⁹. While all three strategies are effective, they also carry the potential for harms such as more frequent follow-up testing, invasive diagnostic procedures, and unnecessary treatment for false-positive results. Despite the effectiveness of these screening methods, only a few African countries with national cervical cancer screening programs have allocated budgets for implementation, with limited adoption of HPV-DNA screening services due to their high cost¹⁰.

In Kenya, low screening coverage has historically impeded program uptake, attributed to stigma, limited awareness, sociocultural barriers, and opportunistic screening practices. However, a policy shift towards integrating screening services into health facilities has begun to address this issue by mandating cervical cancer screening within in-facility service charters. Kenya boasts slightly over 12,000 health facilities, with 5,770 being public. Despite this, HPV testing remains largely unavailable in public facilities, with over 90% relying on visual inspection methods and the remainder on Pap smear¹¹. This limitation stems from inadequate skilled personnel and necessary infrastructure. Beyond sociocultural perceptions, the health system faces constraints stemming from a limited health workforce and various competing priorities, hindering access to cancer screening services in primary care settings. HPV-based screening offers an opportunity to overcome these challenges by enabling a community-based, self-sampling approach.

1.4 The Status of Treatment for HPV-Positive Women

HPV test results indicate whether high-risk HPV types were detected in cervical cells, returning either a negative or positive result. A negative HPV test signifies the absence of high-risk HPV. Conversely, a positive result indicates the presence of an HPV type potentially linked to cervical cancer, serving as a cautionary signal. Although a positive HPV test does not signify cervical cancer, it identifies individuals at heightened risk of developing precancerous lesions in the cervix, which, if untreated, can progress to cervical cancer¹².

Precancerous lesions arise from HPV infection, initiating cellular changes within the cervix. If left unaddressed, these infected cells can lead to cervical cancer up to 15 years post-infection¹³. According to the World Health Organization (WHO), cervical precancerous lesions are categorized into three stages: Cervical Intraepithelial Neoplasia (CIN) 1, CIN 2, and CIN 3. Research indicates that approximately 70% to 80% of stage 1 precancerous lesions either regress spontaneously or remain undetected¹⁴

Key definitions

CIN 1 (low grade) – up to one third of the thickness of the lining covering the cervix has abnormal cells.

CIN 2 (high grade) – up to two thirds of the thickness of the lining covering the cervix has abnormal cells.

CIN 3 (high grade) – the full thickness of the lining covering the cervix has abnormal cells.

WHO recommends three treatment options for cervical precancerous lesions: cryotherapy, Loop Electrosurgical Excision Procedure (LEEP), and Cold Knife Conization (CKC). Cryotherapy or LEEP is recommended for histologically confirmed CIN grade 2 or higher. While cryotherapy is more viable in resource-limited settings, it may be less effective for women living with HIV. In cases of low-grade cervical dysplasia (CIN 1), treatment is often unnecessary as the condition typically resolves on its own, with only about 1% of cases progressing to cervical cancer¹⁴.

1.5 Call to Action

Improved cervical cancer screening is imperative due to its lifesaving potential through early detection, which is particularly crucial in low- and middle-income countries where access to treatment is limited. By detecting precancerous changes or earlystage cancer, screening programs can significantly reduce mortality rates associated with cervical cancer, preventing the progression to advanced disease and the need for more aggressive treatments. Investing in screening programs is cost-effective, as the costs of early detection and treatment are significantly lower than those associated with managing advanced-stage cancer. Additionally, cervical cancer screening empowers women by providing them with knowledge about their cervical health and risk factors, enabling them to take proactive steps to protect themselves. Therefore, improving cervical cancer screening is essential for saving lives, reducing mortality rates, promoting equity in healthcare access, and empowering women through proactive health management.

1.6 Objectives of the Study

The primary objective of this study is to evaluate the costeffectiveness of various cervical cancer detection methods, notably PAP smear, HPV clinical testing, and HPV home-based sampling. By conducting an analysis of the financial implications and benefits associated with these three testing methods, the study aims to provide insights into which approach offers a more efficient and economical means of early detection and prevention of cervical cancer. This study aims to analyze the costs and health outcomes of cervical cancer screening interventions, directly comparing them. Utilizing Return on Investment (ROI) metrics, it will quantify both benefits and costs, offering a comprehensive assessment of the financial implications associated with each testing method.

2. Methodology

2.1 Approach to Computing Target Population

To compute the target population for Pap smear tests and HPV screening within Kenya's context, the following stepwise approach is employed:

- Define the target demographic: The target demographic is defined as women aged 25 to 49, to reflect the age group specified by the Kenya National Cancer Screening Guidelines¹⁵. To gather comprehensive data on awareness and screening rates within this demographic, reputable surveys such as the Kenya Demographic and Health Surveys are utilized.
- 2. Analyze survey data to determine the uptake of cervical cancer screening: Analysis of the Kenya Demographic and Health Surveys (KDHS) reveals that¹⁶:
 - a. Approximately 72.1% of women are aware of cervical cancer.
 - Among the aware women, only 19.4% have undergone cervical cancer screening, with 58.24% opting for Papanicolaou (Pap) tests and 41.76% choosing visual inspection.
- 3. Determine the uptake for Pap smear and HPV DNA screening: Assumptions regarding screening uptake are based on observed trends in screening behavior and the infrastructure in place. Given insights from a pilot study indicating an HPV screening coverage of 27% among the target population, it is inferred that the national screening program would mirror similar patterns identified in the survey data¹⁷. This assumption is rooted in the understanding that the infrastructure and resources allocated to Pap smear testing could facilitate a comparable uptake for HPV screening. Therefore, it is reasonable to infer that 27% of the population currently undergoing Pap testing (58.24% according to the 2022 KDHS) would opt for HPV screening, aligning with the available infrastructure and resources for screening programs.
- **4.** Determine the uptake for HPV self-sample collection: Findings from the pilot roll-out of HPV testing reveal that the self-sample collection approach was more acceptable to the community, particularly among groups with strong cultural beliefs and women who did not present in health facilities¹⁷. It is conservatively assumed that home-based self-sampling will constitute 60% of the total HPV testing, with the remaining 40% opting for clinical-based testing.

2.2 Approach to Computing Costs

The main types of costs considered in our analysis are methodologically listed below:

- 1. Patient transport costs:
 - We estimate patient transport costs based on the average travel expenses in Kenya. For local trips

within the county to reach clinical facilities, we assume a round trip cost of KES 200. For inter-county travel, the assumed round trip cost is KES 1,000. These estimations are grounded in the prevailing transportation costs in the country.

- Transport costs for medical procedures are modeled based on the distribution of healthcare services in Kenya. With 48% of healthcare services delivered by the public sector, 38% by the commercial private sector, and 14% by mission-based hospitals¹⁸, we base our estimations on the availability of procedures in the facilities. For example, Pap smear tests are accessible at the county level, and as a result, patients incur an estimated transportation cost of KES 200.
- Drawing insights from the HPV DNA screening pilot conducted across 27 counties in 2021, we forecast the cross-county travel expenses for HPV clinical testing¹⁹. Approximately 60% of individuals are anticipated to travel to a different county, considering that services are available in 27 out of Kenya's 47 counties. Moreover, in estimating costs for home-based self-sampling, we approximate courier expenses to constitute 60% of the transport costs to facilities. This assumption is informed by a comparative analysis of transportation routes and prevalent courier service providers obtained through desk research.

2. Doctors consultation costs and procedure expenses:

• The estimation of consultation fees and procedure costs involves discussions with a variety of hospitals, including those in the public, mission, and private sectors. Our sampling involved 18 facilities in total, ensuring a comprehensive understanding of the cervical cancer screening expenses incurred.

3. Costs for treatment following positive HPV test results:

- Upon testing positive for HPV, approximately 31% of affected women in Kenya undergo treatment. This is based on National Cancer Control Programme (NCCP) where compliance to treatment of precancerous lesions ranged between 22% and 39%²⁰. Treatment procedures are estimated as follows: approximately 67% undergo colposcopy, 13% undergo LEEP (Loop Electrosurgical Excision Procedure), 18% undergo cryotherapy, and 2% undergo hysterectomy. These estimations are based on survey data collected in a Kenya randomized clinical trial²¹.
- Average costs for undergoing different procedures are estimated using desk research of studies on the procedures, ensuring accuracy and reliability in our cost estimations.

Screening Cost = Transportation costs+ Doctors consultation cost+ Screening cost+ Treatment Costs in HPV positive cases

2.2.1 Approach to Computing Forecasted Costs

The costs are projected over a 5-year period, incorporating key economic and demographic factors. To model the expenses over this timeframe, we utilize the annual inflation rate, as reported by the Central Bank of Kenya, to gauge how costs will evolve over time²². This involves applying the average inflation rate observed over the past year (2023) to estimate the compounded growth of expenses.

Additionally, we consider the population growth rate to illustrate how an expanding population contributes to increased screening costs. By factoring in population growth, we can anticipate the rising demand for screening services and the corresponding financial implications. This approach allows us to provide a comprehensive outlook on how both economic trends and demographic shifts influence the overall costs associated with screening programs.

2.3 Approach to Computing Benefits

The benefits of early detection of cervical cancer are categorized into two main areas, outlined methodologically as follows:

 Cost saved per person from early detection of cervical cancer:

Early detection significantly reduces the financial burden associated with treating advanced stages of cervical cancer. To quantify these savings, we utilize diagnostic test sensitivity, which measures a test's ability to correctly identify individuals with the disease. Drawing insights from various studies, including those conducted in Kenya, India, and England, we observe variations in sensitivity between different screening methods. Notably, HPV testing demonstrates sensitivity ranging from 94.4% to 100%, whereas Pap smear sensitivity ranges from 55.4% to 83.3%^{23,24,25}. Synthesizing these findings, we establish an average sensitivity of 72.3% for Pap smear and 96% for HPV screening. We extrapolate from this data that a significant proportion of cervical cancer cases can be identified early at the HPV-positive stage. Consequently, preventing the advancement to later stages reduces the average expenses associated with treating cervical cancer, resulting in significant economic benefits.

2. Productivity benefits per person from mortality aversion:

Early detection not only saves lives but also preserves productivity by preventing premature deaths. Leveraging the sensitivity of screening tests, we project that up to 72.3% of mortalities can be prevented with pap smear screenings and 96% with HPV screenings based on the sensitivity and specificity of the tests. To estimate the financial contribution of averting mortalities, we consider the current mortality rate, which stands at approximately 67% of cases diagnosed². This allows us to project the mortality that can be averted over time. By employing GDP per capita as a measure, we calculate the financial impact of saving individuals from premature death. This estimation provides insights into the tangible economic benefits derived from early detection and intervention in cervical cancer cases.

Benefits = Cost saved per person from early detection of cervical cancer + Productivity benefits per person from mortality aversion

2.3.1 Approach to Computing Forecasted Benefits

The benefits are projected over a 5-year period, considering critical economic and demographic variables. To model these benefits, we first estimate the annual number of new cervical cancer cases diagnosed. With cancer diagnoses experiencing a steady increase, evidenced by a nearly 30% annual rise between 2012 and 2018, we anticipate a similar growth pattern in the next 5 years¹.

Applying the sensitivity rate allows us to determine the proportion of cervical cancer cases that can be detected early at the HPV-positive stage. This early detection strategy is crucial for mitigating the costs associated with advanced stages of cervical cancer.

To accurately reflect the evolving economic landscape, we adjust the costs associated with advanced cervical cancer rates for inflation. This adjustment involves applying the average inflation rate reported by the Central Bank of Kenya over the past year²², thus providing insights into the compounded growth of expenses over time.

Moreover, in assessing productivity benefits linked to averting mortalities, we integrate considerations of population growth and GDP growth per capita. By factoring in these variables, we gain a comprehensive understanding of the broader economic impact of early detection and intervention strategies for cervical cancer.

2.4 Approach to Computing Return on Investment (ROI)

The return on investment (ROI) quantifies the net gain or loss derived from an investment in relation to its initial cost. This metric serves as a fundamental tool for evaluating the viability and profitability of investment alternatives by analyzing their returns relative to the investment outlay.

The computation method utilized in this analysis is outlined below:



2.5 Study Limitations

Several limitations should be noted. First, the absence of data reflecting the most recent national screening registry poses a challenge. The reliance on screening uptake estimations from the Kenya Demographic and Health Surveys (KDHS) conducted in 2014 introduces further uncertainty, as demographic trends and screening behaviors may have evolved since then. Moreover, the lack of a nationwide survey specifically focusing on HPV screening uptake necessitated the use of assumptions derived from pilot studies to estimate screening uptake rates, potentially introducing bias into the analysis. Additionally, patient outreach costs were not incorporated into the analysis, potentially affecting the accuracy of cost estimations.

Another notable limitation concerns the follow-up protocols and associated costs. The study assumed the availability of colposcopy for cases of HPV positivity and did not account for alternative approaches such as Visual Inspection with Acetic Acid (VIA). This assumption was based on findings from a clinical randomized study conducted in western Kenya, which may not be fully applicable to other regions or settings. Furthermore, the study did not adequately account for variations in followup pathways, particularly among HIV-positive women, and the potential challenges associated with loss to follow-up.

Despite these limitations, it is important to recognize the pragmatic constraints inherent in conducting research within resource-limited settings. The utilization of available data sources and assumptions, while imperfect, allowed for preliminary estimations and insights into HPV and Pap smear screening uptake and associated costs. Additionally, the reliance on findings from prior studies provided valuable context and informed the study's assumptions regarding follow-up protocols. Moving forward, efforts should be made to collect more comprehensive and up-to-date data to enhance the accuracy of future research findings.

3. Findings

3.1 Cost of Cervical Cancer Screening

Pap smear emerges as the screening method incurring the highest total costs over the five-year period, with figures ranging from KES 0.84 billion in the baseline year to KES 1.34 billion in the fifth year. This trend is attributed to the widespread adoption of Pap smear screening, where it has higher uptake rates compared to other methods.

In contrast, clinical HPV testing and home-based HPV selfsampling exhibit lower total costs throughout the study period. Clinical HPV testing incurs relatively lower costs, starting from KES 0.15 billion in the baseline year and gradually increasing to KES 0.24 billion in the fifth year. Similarly, home-based HPV selfsampling shows a comparable cost trajectory, starting from KES 0.22 billion and rising to KES 0.36 billion over the same period.

While Pap smear has the highest total costs, the cost per person is notably lower compared to clinical HPV testing and home-based HPV self-sampling. In the baseline year, the cost per person for Pap smear stands at KES 3,639, whereas clinical HPV testing and home-based HPV self-sampling are significantly higher at KES 7,487 and KES 7,310, respectively.

Number of Women Screened

Cervical cancer screening method	Baseline	Year 1	Year 2	Year 3	Year 4	Year 5
Pap Smear	229,667	234,260	238,945	243,724	248,599	253,571
Clinical HPV Testing	20,378	20,786	21,202	21,626	22,058	22,499
Home Based HPV Self Sampling	30,576	31,179	31,802	32,438	33,087	33,749

Table 2: Total cost for cervical cancer screening methods

Total Cost (KES, Billions)

Cervical cancer screening method	Baseline	Year 1	Year 2	Year 3	Year 4	Year 5
Pap Smear	0.84	0.92	1.01	1.11	1.22	1.34
Clinical HPV Testing	0.15	0.17	0.18	0.20	0.22	0.24
Home Based HPV Self Sampling	0.22	0.25	0.27	0.30	0.33	0.36

Table 3: Total cost for cervical cancer screening methods

Total Cost (KES, Per Person)

Cervical cancer screening method	Baseline	Year 1	Year 2	Year 3	Year 4	Year 5
Pap Smear	3,639	3,918	4,219	4,542	4,890	5,266
Clinical HPV Testing	7,487	8,062	8,680	9,346	10,062	10,834
Home Based HPV Self Sampling	7,310	7,871	8,475	9,125	9,825	10,578

Table 4: Total cost for cervical cancer screening methods (per person)

The observed disparities in total costs and cost per person among cervical cancer screening methodologies have important implications for healthcare policy and practice. Clinical HPV testing and home-based HPV self-sampling, despite exhibiting lower uptake rates and higher costs per person, offer potential benefits such as increased accuracy and convenience. It is worth noting that we have not included a decline in the cost per test for cervical cancer testing methods. This decline could be assumed due to the potential growth in economies of scale over time as the screening rate increases. As such, healthcare stakeholders need to weigh the trade-offs between total costs, cost per person, and the clinical efficacy of different screening methods when designing and implementing cervical cancer screening programs.

3.2 Benefits from Cervical Cancer Screening

Total benefits associated with Pap smear screening increase steadily from KES 1.50 billion in the baseline year to KES 7.86 billion by the end of the fifth year. The higher total benefits associated with Pap smear can be attributed to its higher uptake compared to other screening methods, making it a widely accepted and utilized approach in cervical cancer prevention efforts. Clinical HPV testing and home-based HPV self-sampling also exhibit notable benefits, albeit at varying levels. Clinical HPV testing shows a gradual increase in total benefits, rising from KES 0.30 billion to KES 1.55 billion over the study period. Similarly, home-based HPV self-sampling demonstrates a significant increase in benefits, rising from KES 0.44 billion to KES 3.42 billion.

For HPV clinical testing and self-sampling, the uptake remains significantly below the levels recommended by WHO. The benefits represent the most conservative scenario, as we have not factored in a potential decrease in costs per test with increased screenings. Therefore, these benefits are expected to increase in a scenario where economies of scale are achieved.

Examining benefits per person provides further insights into the individual-level impacts of cervical cancer screening methods. Pap smear, although associated with lower benefits per person compared to HPV testing, offers considerable benefits per person. Starting from KES 6,534 in the baseline year to KES 31,010 by the end of the fifth year. Clinical HPV Testing has higher benefits per person ranging from KES 14,509 to KES 68,856 over the study period. Similarly, home-based HPV self-sampling offers benefits per person ranging from KES 14,509 to KES 101,249, highlighting its effectiveness in reaching underserved populations and increasing screening accessibility.

Total Benefits (KES, Billions)

Cervical cancer screening method	Baseline	Year 1	Year 2	Year 3	Year 4	Year 5
Pap Smear	1.50	2.09	2.91	4.05	5.65	7.86
Clinical HPV Testing	0.30	0.41	0.57	0.80	1.11	1.55
Home Based HPV Self Sampling	0.44	0.93	1.29	1.78	2.47	3.42

Table 5: Total benefits for cervical cancer screening methods

Total Benefits (KES, Per Person)

Cervical cancer screening method	Baseline	Year 1	Year 2	Year 3	Year 4	Year 5
Pap Smear	6,534	8,920	12,179	16,629	22,708	31,010
Clinical HPV Testing	14,509	19,807	27,043	36,924	50,420	68,856
Home Based HPV Self Sampling	14,509	29,793	40,444	54,909	74,557	101,249

Table 6: Total benefits for cervical cancer screening methods (per person)

3.3 Return on Investment from Cervical Cancer Screening

Home-based HPV self-sampling emerges as the most costeffective screening method, showcasing the highest ROI figures over the five-year period. Starting from 1.98 in the baseline year to 9.55 by the fifth year. Clinical HPV testing also demonstrates favorable ROI trends, with figures ranging from 1.94 to 6.36 over the study period. Pap smear, while still valuable, exhibits slightly lower ROI compared to HPV testing modalities. Starting from 1.80 in the baseline year, the ROI for Pap smear gradually increases to 5.89 by the end of the fifth year. While Pap Smear remains a cornerstone of cervical cancer screening, its ROI is surpassed by the more innovative and accessible home-based screening approaches. By prioritizing investments in home-based screening initiatives, healthcare systems can optimize resources and maximize returns while improving access to cervical cancer screening services.

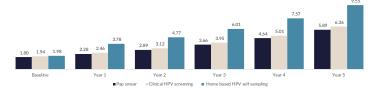


Table 7: Return on Investment on cervical cancer screening tests

4. Discussion

4.1 The Missed Opportunity

The introduction of HPV self-sampling in cervical cancer screening presents a significant opportunity to address challenges in regular screening, particularly in regions with limited healthcare accessibility. Currently, self-sampling for HPV is not widely accessible, and awareness is lacking, resulting in high costs per test. However, increased availability and demand for HPV self-sampling could lower costs per test, boost uptake, and enhance the ROI. The feasibility and effectiveness of home-based HPV self-sampling offer a promising solution to enhance screening uptake, particularly among underserved populations. This approach not only reduces the need for clinical visits but also addresses barriers such as discomfort or embarrassment associated with traditional screening methods.

Similarly, the incorporation of HPV self-sampling into cervical cancer screening programs aligns with global efforts to eliminate cervical cancer, with the WHO recognizing it as a key pillar to reach elimination targets. By embracing innovative screening approaches and prioritizing accessibility and equity in healthcare delivery, countries can bridge the gap in healthcare access and significantly reduce the burden of cervical cancer and other life-limiting conditions, ultimately improving health outcomes and quality of life for all individuals.

The most frequently cited barriers to service delivery included staffing shortages, lack of trained staff, insufficient space, and supply issues. The patient barriers commonly perceived by the staff included inadequate knowledge, wait time, discomfort with male providers, and fear of pain with the speculum exam. Despite multilateral efforts to implement cervical cancer screening, staff face significant challenges to service provision, and increased education is needed for both providers and patients²⁶. Integration of cervical cancer screening into family planning (FP) clinics offers great potential to reach large numbers of reproductive-aged women. Increasing training of healthcare providers and ensuring adequate commodity supplies in FP clinics offer concrete solutions to increase screening in a largely unscreened population²⁷.

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