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RESEARCH ARTICLE

REVISED A Hospital-Based Survey Assessing Facility-Level Factors Contributing to Late-Stage Cervical Cancer Diagnosis: A Mixed-Methods Approach.

[version 2; peer review: 3 approved with reservations, 1 not approved]

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Abstract

Background

In Kenya, cervical cancer is the 2nd commonly diagnosed type of cancer and the top cause of cancer-related deaths among women. Over 50% of cervical cancer cases worldwide are diagnosed at a late stage, with this percentage rising to 80% in developing countries. Poor Health systems are major causes of late-stage diagnosis, leading to low survival rates and increased mortalities among cervical cancer patients. This study focused on determining the facility-level factors that contribute to late-stage diagnosis among cervical cancer patients.

Methods

An analytical cross-sectional mixed method study was conducted to collect data on hospital and referral systems experiences from 139 cervical cancer patients systematically sampled at Kenyatta National Hospital (KNH), using a semi structured questionnaire. In-depth interviews were conducted on 8 Key Informants. Associations between stage at diagnosis (dependent variable) and independent variables were tested using logistic regression at 95% Confidence Interval. Qualitative data was analyzed using content analysis method.

Results

Participants mean age was 51 years. 86 (61.9%) were diagnosed at

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advanced stages III and IV. A higher number of hospital referral instances, facing challenges during the referral process, and prolonged waiting times for diagnostic results were identified as key contributors to late-stage cervical cancer diagnosis.

Conclusion

Delays in diagnosis for most patients is due to poor health and referral systems. The study recommends improving referral systems and encouraging partnerships to decentralize cancer diagnostic.

Keywords
Cervical cancer, Delayed diagnosis, Health-facility level factors, Hospital visits, Referral systems, Diagnosis appointment and results.

This article is included in the European & Developing Countries Clinical Trials Partnership (EDCTP) gateway.

This article is included in the Clinical Medicine gateway.

This article is included in the Cancer collection.

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REVISED **Amendments from Version 1**

I revised the title to remove the term "patient views" to prevent any implication that the study is qualitative. This ensures a more accurate reflection of the study's design.

Vague terminology, such as "delayed diagnosis," was rephrased as "late-stage diagnosis" throughout the manuscript to enhance precision and clarity in describing the condition under investigation.

The study objectives were further clarified and made more specific, improving the reader's understanding of the precise aims and expected outcomes of the research

Terms that were not directly defined, such as "referral challenges," were explicitly clarified in the methodology section to provide context, as there was no dedicated section for defining terms.

A comprehensive review of the manuscript was conducted to identify and correct grammatical and punctuation errors, improving the overall coherence and logical flow of the text.

To address the suggestion to compare findings with global research, I incorporated comparisons with studies from the USA and the UK to demonstrate the consistency and relevance of the results.

I refined the tables by eliminating non-essential elements and consolidating univariate and multivariate results into a single table. This enhanced the presentation of the data and highlighted key differences across analyses.

These revisions aimed to improve the scientific rigor, clarity, and readability of the manuscript.

Any further responses from the reviewers can be found at the end of the article

Introduction

Leading in fourth place globally, among all the cancers that affect women, cervical cancer records approximately 660,000 new cases and nearly 360,000 new deaths worldwide[1,2]. It has been proven that approximately 90% of these cases occur in developing countries[3], with Africa reporting close to 125,000 new cases annually, and is ranked second in causing cancer-related deaths, mostly among women age–14–44 years[4]. As of 2022, cervical cancer comes second after breast cancer as the commonly diagnosed type of cancer among women in Kenya, with about 6,000 new cases annually and is the major cause of cancer-related deaths among women recording 3,600 deaths., accounting for close to 12% of all cancer-related deaths among women in Kenya[5].

Literature shows that the stage of cancer at the time of diagnosis is a vital prognostic factor that influences cancer treatment outcomes[6]. Delays in cancer diagnosis increase the risk of poor outcomes[7]. Early-stage diagnosis (Stages I and II) is associated with a 98% 5-year survival rate, while late-stage diagnosis (Stages III and IV) is associated with lower rates (17% 5-year survival rate)[7]. Cervical cancer is often diagnosed at advanced stages, defined in this study as FIGO stages III and IV. Globally, the prevalence of late-stage diagnosis of cervical cancer is more than 50%, with this proportion rising to approximately 80% in developing countries[6,7]. Despite strategies that have been put in place to enhance early detection, such as creating awareness and routine screening, cervical cancer remains a threat to many sexually active women in Africa[8].

Early-stage diagnosis is often facilitated by functional health systems that support effective patient management, including timely referrals from under-resourced facilities to better-equipped hospitals, where advanced diagnostic services are available. Conversely, inadequate health systems can result in delays within primary healthcare, contributing to late-stage cancer diagnoses[7,9,10]. In Kenya, limited research has explored the impact of poor health systems on delays that lead to late-stage cervical cancer diagnoses, which are associated with high mortality rates due to suboptimal treatment outcomes. This study aimed to assess the association between late-stage diagnosis and various health facility-level factors.

Methods

This was a hospital-sited, analytical, cross-sectional mixed method study (with both quantitative and qualitative techniques used), conducted between September to November 2023, at the Kenyatta National Hospital (KNH), a National Referral and Teaching Hospital, that offers both preventative and curative services for cancer patients referred from all over Kenya[11]. Systematic sampling was used to select 139 cervical cancer inpatient and outpatient patients, diagnosed and receiving treatment at the KNH, aged above 18 years, and diagnosed within one-year prior time of data collection to minimize recall bias[12]. Patients whose medical records lacked clear staging information, those diagnosed with other cancer types, those with recurrent cervical cancer, those in palliative care, those with psychotic health issues, and those who were unwilling to participate in the study were excluded. The participants were interviewed using a semi-structured questionnaire[13], with questions regarding their hospital and referral systems experiences, such as the type of medical facility they visited first, number of hospital visits they made before diagnosis, if they were referred to KNH, number of referral times, type of any referral challenges they faced, and the period taken to get diagnosis appointments and results. This allowed for quantitative data collection. A Key Informant Guide was used to conduct Key Informant Interviews (KIIs), to enable in-depth qualitative data collection from 8 Key Informants, such as; Medical, Radio Oncologists, departmental nurses and social workers, in audio recorded sessions. The qualitative data was collected to support the quantitative findings in triangulation[14].

The key outcome of late-stage diagnosis was stage at diagnosis, categorized as either early (stages IA to IIB) or late-stage (IIIA and IVC) using the International Federation of Gynecology Obstetrics (FIGO) staging for cervical cancer that is based on the cancer's size, location and spread[15]. The stage at diagnosis was retrieved as the stage of malignancy recorded by the doctor in the patients' files, using abstraction forms. Statistical analyses were performed using Stata version14.2 (https://www.stata.com/)[16]. The association between late-stage diagnosis and facility-level factors was tested by logistic regression test at 95% Confidence Interval[17]. Odds Ratios and p-values were reported. Unadjusted logistic regression was done for bivariate analysis to examine the crude association between each variable

and late-stage diagnosis Crude Odds Ratios (CORs) and p-values at 95% Confidence level were reported. Potential predictor variables were selected for the MLR models, based on bivariate analysis p-value ($p<0.05$), to analyze independent variables with a statistically significant association to late-stage cervical cancer diagnosis. Audio recordings for qualitative data were transcribed verbatim, transcripts were verified, and then content analysis was conducted using NVIVO 14 (https://lumivero.com/resources/free-trial/nvivo/)[18].

Results

Sociodemographic characteristics

The sociodemographic characteristics of the 139 participants are illustrated in Table 1. The mean age was 51 years. Majority of the 49(35.25%) participants were aged between 40–49 years. More than half 88(63.31%) were married, and 95(86.35%) were educated up to the primary level. Less than half of the 54 participants (38.85%) reported being employed. (Table 1).

Prevalence of Late-Stage diagnosis

The Prevalence of late-stage diagnosis was 61.87% as 86 of the 139 participants were diagnosed at stages IIIA to IVC as illustrated in Figure 1. Qualitatively, seven of the eight key informants confirmed that most KNH patients were diagnosed at advanced stages III to IV. Late-stage diagnosis was prevalent among older participants (>50 years), those with a lower level of education and those lacking employment/income. Figure 1.

Facility-level factors

Distribution of participants across of health facility factors

Table 2 illustrates the distribution participants across the facility factors. Over half of the participants 91(65.67%) first sought medical care from public health facilities, followed by 40(28.78%) who went to private health facilities, and 8(5.76%) who sought help from local chemists or traditionalists. Less than half 49(35.25%) of the participants visited the hospital five times or more before being diagnosed with cervical cancer. Regarding referrals, a total of 125(89.93%) participants were referred from lower-level facilities to the KNH, with 58(46.4%) reporting that they were referred twice or more. Late-stage diagnosis was prevalent among those were referred twice ore more (81.03%). More than half of those who were referred to 72(57.6%) reported facing referral challenges that hindered access to appropriate and proper medical care, thus delaying their diagnosis. A proportion of 70.83% of those who faced referral challenges reported to have been diagnosed at either stage III or IV. Most patients who faced challenges reported a lack of finances (40) as the major challenge they faced, followed by misdiagnosis (15) and prolonged appointments (14) as shown in Figure 2. Those who reported misdiagnosis reported to have been diagnosed with various illnesses such as vaginal infections, STIs, postmenopausal bleeding, hormonal contraceptive side effects, and fibroids, among other health issues. (Figure 2)

Most participants 64(46.04%) reported having received their diagnostic results in less than two weeks, while 32(23.02%) reported having received results in over a month. (Table 2).

Table 1. Summary patients' socio-demographic characteristics.

Variable	Early (%) n=53	Late-stage (%) =86
Age in years		
<40	13(59.09)	9(40.91)
40-49	24(48.98)	25(51.02)
50-59	13(30.95)	29(69.05)
60-69	2(11.11)	16(88.89)
70 and above	1(12.50)	7(87.50)
Ethnicity		
African	53(38.13)	86(61.87)
Religion		
Christian	53(38.13)	86(61.87)
Marital Status		
Married	37(42.05)	51(57.95)
Divorced/Widowed	8(28.57)	20(71.43)
Single	8(34.78)	15(65.22)
Residence		
Urban	23(38.98)	36(61.02)
Semi-urban	7(29.17)	17(70.83)
Rural	23(41.07)	33(58.93)
Education Level		
Primary and below	31(32.63	64(67.37)
High school	17(50.00)	17(50.00)
Tertiary	5(50.00)	5(50.00)
Employment Status		
Employed	28(51.85)	26(48.15)
Not employed	25(29.41)	60(70.59)

Association between health facility level-factors by delayed Cervical Cancer diagnosis

A structured approach was adopted for the association analysis. Bivariate analysis was performed to examine the relationship between each independent variable individually and the binary dependent variable (stage of diagnosis) using logistic regression, and to identify potential predictors of the outcome at a 95% confidence level ($p < 0.05$). Variables found to be statistically significant ($p <0.05$) were selected for the multivariate logistic regression test model to show the independent variables that were independently associated with late-stage diagnosis after controlling for confounders[19].

Across the seven facility factors, four were found to be potential risk factors in the bivariate analysis. Being referred to KNH

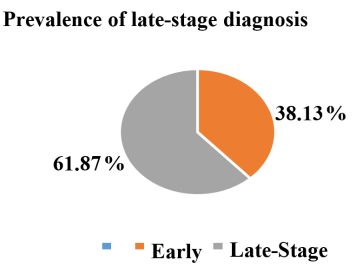


Figure 1. Prevalence of Late-Stage Diagnosis. Figure 1 illustrates the prevalence of delayed diagnosis (67.81%) among cervical cancer patients at KNH. The pie chart is divided into two segments, each representing the percentage (size) of patients either diagnosed early or late. Data was collected from 139 participants, 86 who were found to be diagnosed late, while 53 were diagnosed early, as defined by the study.

was not found to be statistically significantly associated with late-stage diagnosis of cervical cancer in this study. Although, among the 125(89.93%) participants who reported to have been referred from lower-level facilities KNH, 79(63.20%) were found to have been diagnosed at stage III or IV.

Patients who had been referred two times and more were potentially found to be 4.7 times more likely to have late-stage diagnosis compared to those who were only referred once. Those who reported to have faced referral challenges were potentially found to be 2.2 times more likely to be diagnosed at late stages than those who reported not to have faced any referral challenges. Referral challenges were defined as any hospital related barriers that they faced during the referral process than may have contributed to delays during diagnosis. While the majority of the patients reported that their diagnosis took less

Table 2. Distribution of participants across of health facility factors.

Variable	Early (%) n=53	Delayed (%) n=86
First Hospital Type Visited		
Private	15(37.50)	25(62.50)
Public	36(39.56)	55(60.44)
Other	2(25.00)	6(75.00)
Number of Hospital visits		
Once	12(41.38)	17(58.62)
Twice	10(45.45)	12(54.55)
3-4 times	14(35.90)	25(64.10)
5times and above	17(34.69)	32(65.31)
If Referred		
Yes	46(36.80)	79(63.20)
No	7(50.00)	7(50.00)
Number of Referral times		
Once	35(52.24)	32(47.76)
Two and above	11(18.97)	47(81.03)
Faced Any Referral Challenges		
Yes	21(29.17)	51(70.83)
No	25(47.17)	28(52.53)
Time taken to get Diagnosis Appointment		
<2 weeks	48(40.34)	71(59.66)
2 weeks- 1 Month	1(8.33)	11(91.67)
I month and above	4(50.00)	4(50.00)
Time taken to get Diagnostic Results		
<2 weeks	31(48.44)	33(51.56)
2 weeks- 1 Month	16(37.21)	27(62.79)
I month and above	6(18.75)	26(81.25)

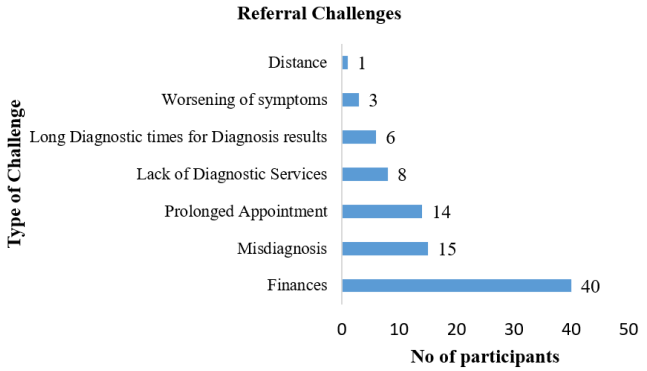


Figure 2. Distribution of Referral Challenges. Figure 2 is a horizontal bar chart showing the different hospital referral challenges that the cervical cancer patients at KNH who reported to have been referred from another hospital to KNH for diagnosis, faced during the referral process. It also shows the distribution of patients across the challenges.

than two weeks, 36(23%) of the participants reported that their diagnosis took longer than one month, with 26(81.25%) of them being diagnosed at advanced stages. Patients who reported that their diagnosis appointment took 2 weeks to1 month were potentially found to be 7.4 times more likely to be diagnosed at late stages than those who reported that their diagnosis appointment took less than 2 weeks, while patients whose diagnostic results took 1 month and above were potentially found to be 4.1 times more likely to be diagnosed at late stages than those whose results took less than 1 month.

Table 3 illustrates a multi-collinearity check that was performed on the significant factors that were found to be potential predictors from the bivariate analysis, and none showed any collinearity[20]. Additionally, the study assumed that the observations were independent of each other, which is another crucial assumption in regression analysis[19]. (Table 3).

Table 4 summarizes the relationship between late-stage cervical cancer diagnosis and facility-level factors, assessed using logistic regression. Both bivariate and multivariate results are presented to compare how the multivariate logistic regression (MLR) model performed after adjusting for potential confounders.

An adjusted multivariate logistic regression model was used to run the four factors, and three remained to be independently statistically significantly associated with late-stage diagnosis; the number of referral times, facing referral challenges and time taken to get diagnostic results. The variable "First hospital type visited", was used as a covariate as it was identified to be a potential confounder at this level. The first hospital that a patient visited after experiencing symptoms, would dictate if the patient would receive care there primarily or be referred to a higher-level hospital. This would thus expose the patient to referral process, predisposing them to referral challenges and systemic delays, which were being investigated in the MLR model. The covariate was however excluded from the final model table.

The Pseudo R squared was 0.1942, meaning that the logistic regression model was a good fit, that explained 19% of the variability in late-stage diagnosis[21]. The probability associated with the chi-square statistic (Prob > chi2), used to test the significance of predictors in a model was 0.0001, supporting the conclusion that the predictors improve the model fit[17]. The Hosmer-Lemeshow test was done to perform the model's goodness of fit test, and the p-value associated with chi-square statistic was greater than 0.05 (Prob>Chi2=0.1857), indicating that the model was a good fit, appropriate for the data and type of analysis done (logistic regression), has a high predictive validity as its predicted probabilities closely match the observed outcomes, lacks systematic bias in its predictions and improves the confidence to draw conclusions form the analysis[22].

Qualitative findings

Figure 3 illustrates the qualitative findings from the KIIs, which aligned with the confirmed associations between referral times, referral challenges, prolonged appointments, and delayed results with late-stage diagnosis. It was reported that due to the referral challenges that patients face from local facilities to KNH, such as misdiagnosis and cost of diagnosis, patients often reach the facility when the disease has progressed to advanced stages and incur more diagnostic costs.

"Like, if someone has irregular bleeding for long periods and they visit a smaller hospital, they are misdiagnosed with things like postmenopausal bleeding, ...this can make it to take longer for them to be correctly diagnosed." (KII_6RO)

"Each referral means an extra cost for the patient. For example, KNH asks for new scans from a referred patient because most of the time the patient comes in delayed...so they ask for another scan to get a more current state of the disease." (KII_8MO)

"...there is poor diagnosis from peripheral facilities due to lack of specialized personnel. A clinician should have a high index of diagnosis" (KII_7MO)

Appointment dates for diagnosis also take too long because of congestion owing to the high number of patients.

Do you know if you came here today for diagnosis you will be booked to have scanning or MRI in two months, that is the least time...they say patients are many...biopsy take even longer than 2 months...Only those who can afford scanning in private facilities do it quicker" (KII_5N). (Figure 3)

Discussion

Prevalence of late-stage diagnosis

The study found that most participants were diagnosed at late stages of cervical cancer. The prevalence of late-stage diagnosis found in this study (61.87%) was slightly lower than that of a cross-sectional study conducted in Uganda (66%) and close to that of a population study conducted in Ethiopia (60.4%)[23,24]. Closely related is another a hospital-based study conducted in Scotland, United Kingdom (UK), reported that 68% of patients were diagnosed at late stages. However, it is important to note a significant difference in this study's

Table 3. Multi-collinearity checks among health facility-level factors.

	Referral times	Referral challenges	Diagnosis appointment	Diagnosis results
Referral times	1			
Referral challenges	0.0517	1		
Diagnosis appointment	0.0431	0.1738	1	
Diagnosis results	0.1098	0.0794	0.1791	1

Table 4. Logistic Regression of significant predictors associated with late-stage diagnosis.

Variable	Unadjusted OR	p-value	Adjusted OR	p-value
Number of Referral times				
Once	Ref			
Two and above	4.673	**0.000**	4.685	**0.001**
Faced Any Referral Challenges				
Yes	2.168	**0.041**	2.398	**0.048**
No	Ref			
Time taken to get Diagnosis Appointment				
<2 weeks	Ref			
2 weeks-1 Month	7.437	**0.059**	6.471	0.109
1 month and above	0.676	0.592	0.239	0.142
Time taken to get Diagnostic Results				
<2 weeks	Ref			
2 weeks-1 Month	1.585	0.252	1.202	0.712
1 Month and above	4.071	**0.007**	3.983	**0.026**

***Statistically significant at P-value of less than 0.05 Covariate (First hospital type visited)**

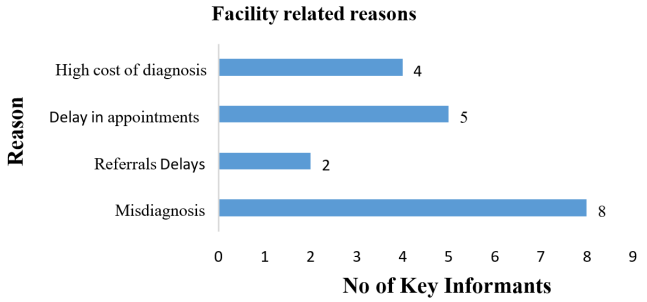


Figure 3. Facility reasons contributing to late-stage diagnosis; KIIs views. Figure three is a representation of the Key Informant views on reasons that may facilitate delayed diagnosis or hinder cervical cancer patients from accessing early care for timely diagnosis. This views were triangulated to support the qualitative findings and provide in-depth understanding of the study findings.

definition of late-stage diagnosis, which was classified as Stage IIB to Stage IVC[25].

Facility-level factors

In this study, 90% of participants sought medical help from other facilities before being referred to the KNH. The inadequacy and centralization of diagnostic facilities in Kenya is one of the major barriers to accessing cancer testing, especially in local facilities[26], leading to patients being referred to better-equipped facilities to access quality diagnostic services. While assessing the referral dynamics, this study found that patients referred twice or more were likely to face various referral challenges and were found to be more likely to have late-stage diagnosis, compared to those who were only referred once and who faced none or fewer referral challenges. Patients were reported to have experienced misdiagnoses of other diseases, such as fibroids, postmenopausal bleeding, and infections. Medical staff noted that several medical personnel from local facilities were less equipped with skills and that they lacked a high index in suspecting cancer cases; thus, there were a high number of misdiagnosed cases. These findings were in agreement with another study, in which almost half of the

participants were referred more than once, and 35% of them blamed medical personnel at local facilities for having misdiagnosed them with other diseases and lack of diagnostic equipment as major referral challenges[9]. Another study conducted in the United States found that patients referred for evaluation, took approximately two months to be diagnosed with cervical cancer. This highlights delays in the time to diagnosis even after a symptomatic patient has entered the healthcare system[10]. This could be explained by challenges presented by poor referral systems, such as high cost of diagnosis, misdiagnosis due to lack of specialized personnel and diagnosis equipment, which may contribute to delays in primary health care[9]. The availability and accessibility of effective cancer diagnostic equipment, are vital hospital factors that improve early diagnosis in cancer patients[9]. Inadequate access to screening and diagnostic services and trained medical personnel, especially in rural settings, forces patients to travel long distances to seek better primary healthcare[9,26]. Qualitatively, patients had to incur extra financial costs at all referral stages as they were required to pay for consultations, tests, and treatment. Referrals have also led to inconsistencies in medical information due to misplacement of patients' medical records. This would further lead misdiagnosis and financial burden on patients. Qualitatively, a previous study reported that inadequacy of patient information by healthcare providers is a factor that may contribute to late-stage diagnosis[27].

This study also found that longer waiting periods for diagnosis appointments and results lead to late-stage diagnosis. These findings are consistent with those of a study that reported that delays in diagnosis hinder primary healthcare, because medical care decisions are dependent on them[9]. Centralization of diagnostic and treatment equipment in major government hospitals, causes patients congestion, due to higher patient to medical personnel ratios and few equipment for diagnosis[26]. Needy patients are required to travel long distances to seek diagnostic services[26]. Qualitative findings revealed that due to the high number of cancer patients at KNH, patients take longer to get diagnosis appointments and scanning or biopsy results. During this waiting period, the disease progresses further leading to worsening of symptoms, especially in late-stage patients. These delays could implicate more treatment financial burden on patients. Delays in diagnosis also hinder primary healthcare, as medical care decisions are dependent on them[9]. This study found that patients who are able to afford private facilities are able to quickly track this process and receive early diagnosis and treatment, because private facilities experience less congestion as only patients who can afford their services visit them.

Conclusion

The study identified gaps in the organization of health referral systems and systemic delays in appointments, and the results. With these gaps, poor health systems are a major hindrance to the availability and access of quality medical care, leading to delays in diagnosis. Measures such as decentralization of HPV screening and cancer diagnosis resources, including trained medical officers, are recommended to lessen the burden of referral challenges and diagnosis delays while targeting women from all socio-demographic settings to improve timely diagnosis. Further studies should assess misdiagnosis as major challenge in cervical cancer diagnosis.

Study limitation

The study was limited by recall issues from participants who may not have clearly remembered the date and stage of their diagnosis. Recall bias was minimized by including only participants diagnosed within a year before data collection. The study also adopted abstraction forms to obtain clear information on the date and stage of diagnosis from patients' medical files, thus minimizing recall bias.

Ethical approval and consent

Ethical clearance and approval were obtained from the JKUAT and KNH-University of Nairobi (UON) Ethical Review Committees (ERCs) under approval numbers JKU/ISERC/02316/0818 and P522/06/2023, on 23rd February and 24thAugust 2023, respectively. A Research permit was also obtained from the National Commission for Science, Technology & Innovation (NACOSTI) under license number NACOSTI/P/23/24644, on 17th April 2023. A study certificate was also issued by the KNH Medical Research Department, to allow the registration of the research project and data collection process, on 31st August 2023. Authorization to access and use patient contact information to seek consent, schedule interviews and access hospital medical records for data, was sought from the KNH Administration. Patients available physically at the hospital as either in or out patients and gave written consent to participate in the study, were interviewed face to face by trained Research Assistants (RAs), while those who were unavailable physically gave oral consent during telephone interviews. Permission to waive written consent for telephone interviewed participants was sought in the proposal approved by the KNH-UON ERC. Participants were interviewed in privacy, and data collected was handled with confidentiality through the use of identity codes to conceal the patient identities and by limiting access to the raw data collected to the Principal Investigator only.

Data availability

Underlying data

Dryad: Research data on health facility-level factors that contribute to delayed diagnosis of cervical cancer, https://doi.org/10.5061/dryad.dz08kps5m[12]

This project contains the following underlying data:

- Data.xlsx

- README.md

Data are available under the terms of the Creative Commons Zero "No rights reserved" data waiver (CCO 1.0 Public domain dedication)

Extended data

Dryad: Research data on health facility-level factors that contribute to delayed diagnosis of cervical cancer, https://doi.org/10.5061/dryad.dz08kps5m[12]

This project contains the following extended data:

- INFORMED CONSENT FORM.pdf

Data are available under the terms of the Creative Commons Zero "No rights reserved" data waiver (CCO 1.0 Public domain dedication)

Software availability statement

The quantitative analysis in this article was performed using Stata version 14.2, a proprietary statistical software (https://www.stata.com/). For those without access to Stata, equivalent analyses can be performed using open-source alternatives such as R (https://cran.r-project.org/bin/windows/base/).

The qualitative analysis in this article was performed using NVIVO 14.2, a proprietary qualitative data analysis software. For more information about NVIVO, visit the NViVO website (https://lumivero.com/resources/free-trial/nvivo/). For those without access to Stata, equivalent analyses can be performed using open-source alternatives such as Taguette (https://www.taguette.org/).

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Current Peer Review Status: ✗ ? ? ?

Version 2

Reviewer Report 20 August 2025

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BERNARDO JOSE VEGA CRESPO
Universidad de Cuenca, Cuenca, Ecuador

Dear Authors,
This is an interesting paper that highlights the needs of women in accessing specialized health facilities for the treatment of cervical cancer at late stages, as well as the challenges they face. Identifying factors related to late-stage diagnosis of cervical cancer is essential to reducing mortality.

General Comments

Methods

- You mentioned that “systematic sampling was used to select 139 cervical cancer inpatients and outpatients.” Please explain what is meant by systematic sampling, and clarify how patients were selected. Was it solely through medical records?
- You stated that “participants were interviewed using a semi-structured questionnaire.” Were all recruited participants interviewed, or only those with stage III cervical cancer? Please clarify.
- Was the questionnaire you used previously validated elsewhere, or was it developed specifically by the researchers for this study?
- Were there any specific selection criteria for the key informants?
- Please clarify why stage IIB is considered an early stage in your study, given that some protocols define surgical treatment up to stage IIB as the upper limit.
- How did you define late stage? Some literature considers stage IIA and lower as early (since surgery can still be performed), and stage IIB and above as late stage.

Results

- For “women below 40,” how young were the participants?
- Please clarify how the health system functions, to provide context as to why a patient might need to be referred multiple times before accessing specialized care.
- Where were the diagnostic appointments carried out—at primary health centers? Were diagnostic results also provided at the same facility? How much time typically elapsed between referral from a primary health center and access to higher-level care or treatment?
- In Figure 2, regarding the reported challenges: were women able to select more than one

challenge?
- You mentioned that “patients who reported that their diagnostic appointment took 2 weeks to 1 month were 7.4 times more likely to be diagnosed at late stages than those whose appointment took less than 2 weeks.” Could you explain this finding? The literature indicates that it usually takes 10–15 years for a premalignant lesion to progress to invasive cervical cancer. For example, stage IA1 disease would not typically advance so quickly to stage IIB or higher.

Discussion
- In the discussion, some results are described again rather than being analyzed in depth.
- It would be useful to include a reflection on what might be considered appropriate waiting times. For instance, would you consider 2 months too long?
- Perhaps the problem is more closely related to delayed diagnosis and low coverage of cervical cancer screening.

Is the work clearly and accurately presented and does it cite the current literature?
Partly

Is the study design appropriate and does the work have academic merit?
Partly

Are sufficient details of methods and analysis provided to allow replication by others?
Partly

If applicable, is the statistical analysis and its interpretation appropriate?
Partly

Are all the source data underlying the results available to ensure full reproducibility?
Yes

Are the conclusions drawn adequately supported by the results?
Partly

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Cervical cancer, Sexual and reproductive health, Ob/Gyn

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.

Version 1

Reviewer Report 16 December 2024

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Rogers Kajabwangu
Mbarara University of Science and Technology, Mbarara, Western Region, Uganda

General comment: The work is novel with strong methodology. The title can be improved by removing the phrase "Patients' views at the end. Keeping it there might imply that the study is purely qualitative.
Abstract: Generally well-written. In the results section, avoid starting sentences with numerical figures.
Background: Fairly well-written "Leading in fourth place" does not sound correct. Please revise. Cervical cancer should be written in lower case throughout including the beginning letters. The phrase "This study assessed the association between delayed diagnosis and patients' experiences at the health facility level at Kenyatta National Hospital (KNH)" does not reflect the actual objectives of the study
Methods:. Please rephrase. The classification of stage in which stage iib is classified as early stage is inaccurate. Please either revise or provide an appropriate reference for your classification. Independent variables such as referral challenges" which are not directly clear, should be defined
Results: The description of table 1 needs to be rewritten with better grammar. For example, "A majority of participants" should be "The majority of participants". The punctuation also needs to be worked on. From the table, remove variables like "ethnicity" which don't have varying groups. The results for the qualitative part of the study should be presented after all the results for the quantitative part have been presented. The paragraph at the beginning of table 3 , ie "A structured approach was adopted for the analysis. Bivariate analysis was performed to examine the relationship between each independent variable individually and the dependent variable (delayed diagnosis) using binary logistic regression, and to identify potential predictors of the outcome at a 95% confidence level ($p < 0.05$). Variables found to be statistically significant ($p < 0.05$) were selected for the multivariate logistic regression test model to show the independent variables that were independently associated with delayed diagnosis after controlling for confounders" is misplaced as it belongs to the methods section. In the tables from logistic regression, there's no need to describe proportions. It is prudent to stick to measures of association. In table 4, which measure was used for multicollinearity check? Its preferrable to have one table showing both bivariate and multivariable analysis. P-values and odds ratios are sufficient to describe association. The rest such as Z-statistic should be removed.
Discussion: The discussion is fairly well-written**.** The subheadings should be removed. I suggest that you mention the result for each aim separately and follow it up with a comparison with previous studies if any. Under limitations, the phrase "recall issues" should be replaced with a more appropriate one.
Conclusion: The conclusion is well-written.

Is the work clearly and accurately presented and does it cite the current literature?
Partly

Is the study design appropriate and does the work have academic merit?

Yes

Are sufficient details of methods and analysis provided to allow replication by others?
Partly

If applicable, is the statistical analysis and its interpretation appropriate?
Yes

Are all the source data underlying the results available to ensure full reproducibility?
Yes

Are the conclusions drawn adequately supported by the results?
Yes

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Cervical cancer

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.

Reviewer Report 10 December 2024

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Diane M Harper
University of Michigan School of Medicine, Ann Arbor, USA

This is a single-site registry analysis among 139 selected cervical cancer patients diagnosed within the prior year in Kenya.

The data from Kenya are important to analyze. But there is a global set of data about who gets cervical cancer, who has prior screens, what age are the cancers diagnosed at, what stages are the cancers, what treatments were offered, what the mortality rate/survival rate was after treatment. This project needs to integrate their average age of diagnosis to the international data to highlight how different (or similar Kenya is). The fact that in the US 52% of cervical cancers come from women with no screening and are only detected through symptoms, is nearly the same as you are presenting in this paper in Kenya where the statistics feel similar.

This paper could be more useful than just highlight the Kenya statistics, by comparing how the Kenya data interleaf or compare with the global data.

Is the work clearly and accurately presented and does it cite the current literature?
Partly

Is the study design appropriate and does the work have academic merit?
Yes

Are sufficient details of methods and analysis provided to allow replication by others?
Yes

If applicable, is the statistical analysis and its interpretation appropriate?
Yes

Are all the source data underlying the results available to ensure full reproducibility?
Yes

Are the conclusions drawn adequately supported by the results?
Yes

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: cervical cancer prevention

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.

Reviewer Report 19 September 2024

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Leon C Snyman
University of Pretoria, Pretoria, Gauteng, South Africa

Thank you for the opportunity to review the manuscript.

Having read the manuscript, it seems to me that the authors use "advanced staged disease (Stages III and IV)" and "delayed diagnosis" as synonyms, and "early diagnosis" and "early stage (I and II)" as synonyms. This of course is incorrect. The main reason for women being diagnosed with advanced stage cervical cancer is the absence of a screening programme. In the health system where there is no cervical cancer screening programme, women are diagnosed with the disease when they become symptomatic. A woman can be symptomatic, have experienced no delay in making the diagnosis, and still be diagnosed with stage III or IV disease. It is therefore not

accurate to assume that all women diagnosed with advanced stage disease has had a delayed diagnosis or that all women diagnosed with stage I or 2 have had no delay in the diagnosis, because it is possible to have a delayed diagnosis and still be diagnosed in early stage of the disease.

To address the issue of "delayed diagnosis of cervical cancer" it needs to be defined what is a delay before the factors that contribute to it can be investigated, comparing those who had no delay to those had a delay.

Looking at these factors and even if they are successfully addressed, will not impact on the lives of Kenyan women. Primary prevention (vaccine) and secondary prevention (screening for cervical cancer) will impact significantly and will make a huge difference to cervical cancer death rates in countries with poor health care resources.

Is the work clearly and accurately presented and does it cite the current literature?
Partly

Is the study design appropriate and does the work have academic merit?
No

Are sufficient details of methods and analysis provided to allow replication by others?
Partly

If applicable, is the statistical analysis and its interpretation appropriate?
I cannot comment. A qualified statistician is required.

Are all the source data underlying the results available to ensure full reproducibility?
Yes

Are the conclusions drawn adequately supported by the results?
Partly

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Gynaecological oncology, HPV, cervical cancer, general gynaecology, minimally invasive access surgery

I confirm that I have read this submission and believe that I have an appropriate level of expertise to state that I do not consider it to be of an acceptable scientific standard, for reasons outlined above.

Author Response 19 Sep 2024

Marthaclaire Zammit

Thank you for this first peer review. My understanding of the reviewer's feedback is clear.

There is a requirement to distinguish between "stage at diagnosis" and "delayed diagnosis" effectively, which are indeed separate concepts. The feedback seems more about the clarity of definitions rather than a flaw in the methodology itself.

I do understand that the reviewer points out that; Stage at Diagnosis (I-IV): Refers to how advanced the cancer is at the time of diagnosis. A woman could be diagnosed at stage I or II (early) or stage III or IV (advanced), but this does not inherently speak to whether her diagnosis was delayed.

Delayed Diagnosis: Refers to the time it took for a patient to be diagnosed after the onset of symptoms or after a first healthcare visit. A delay means there was a significant gap between symptom onset or healthcare seeking and the actual diagnosis.

Therefore, A woman can be diagnosed at an advanced stage (III or IV) without experiencing a "delay" in diagnosis if she only presents to healthcare when symptomatic (as seen in settings without screening programs).

Conversely, a woman can experience a delayed diagnosis but still be diagnosed at an early stage (I or II). While this does make sense, marking the research paper as not of acceptable scientific standards, would be an outright dismissal of the rigor of its methodology, strength of data analysis, and relevance of its findings. The paper CLEARLY states how "Delayed Diagnosis"" was defined and assessed, in this specific research.

I believe, the main concern is how delayed diagnosis was defined, which is different from how the reviewer views it. This can be reviewed. Constructive feedback on how to "word" it better would be much appreciated.

In revising the title to; **''Determinants of Late-Stage Cervical Cancer Diagnosis: A Focus on Health facility Barriers"** or **"Late-Stage Cervical Cancer Diagnosis: Investigating the Role of health-facility level Barriers",** and work on the wording, this might alleviate concerns from other readers about confusion around the terms.

Thank you.

Competing Interests: No competing Interest