# HPV-DNA test access based on self-collection of vaginal samples from women living with HIV/AIDS: pilot implementation in Brazil

## *Autocoleta vaginal por mulheres vivendo com HIV/AIDS para testagem de HPV-DNA: implantação piloto no Brasil*

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**ABSTRACT**

**Introduction:** Women living with HIV/AIDS have a higher frequency of anogenital neoplasms resulting from human papillomavirus (HPV) infection. The World Health Organization recommends that cervical cancer screening uses molecular tests that amplify viral genetic material, such as HPV-DNA. In addition to collection by health professionals, self-collection of vaginal samples is a useful tool for expanding access to testing. **Objective:** To describe the results of the pilot study that evaluated the acceptability of self-collection of vaginal samples and the applicability of offering HPV-DNA tests with self-collection of vaginal samples for women living with HIV/AIDS in Brazil. **Methods:** Descriptive cross-sectional study involving women living with HIV/AIDS treated in eight HIV-specialty healthcare facilities distributed in all regions of the country from May 2021 to May 2022 and a central laboratory. Vaginal self-collection was offered, and participants were interviewed about sociodemographic data and impressions of self-collection. **Results:** In total, 1,919 women living with HIV/AIDS with an average age of 45 years participated in the study. Some type of HPV was detected in 66% (1,267) of cases. The majority (71.9%) said they preferred self-collection to sample collection by health care professionals. Only 53.8% of participants underwent cytology at the appropriate frequency, as recommended by the protocol. **Conclusion:** The results may support the implementation of molecular biology tests to detect HPV in women living with HIV/AIDS, including the possibility of vaginal self-collection, promoting increased access to cervical cancer screening.
**Keywords:** HIV seropositivity. Human papillomavirus viruses. Mass screening. Uterine cervical neoplasms. Health services.

**RESUMO**

**Introdução:** Mulheres vivendo com HIV/AIDS possuem maior frequência de neoplasias anogenitais decorrentes da infecção pelo papilomavírus humano (HPV). A Organização Mundial da Saúde recomenda que o rastreio de câncer do colo do útero seja utilizado por testes moleculares que amplificam o material genético viral, como o HPV-DNA. Além da coleta por profissionais da saúde, a autocoleta de amostras vaginais consiste em uma ferramenta útil para ampliação do acesso à testagem. **Objetivo:** Descrever os resultados do estudo piloto que avaliou a aceitabilidade da autocoleta de amostra vaginal e aplicabilidade da oferta de testes HPV-DNA com autocoleta de amostras vaginais para mulheres vivendo com HIV/AIDS no Brasil. **Métodos:** Estudo transversal descritivo envolvendo mulheres vivendo com HIV/AIDS atendidas em oito serviços ambulatoriais distribuídos em todas as regiões do país no período de maio/2021 a maio/2022 e um laboratório central. Realizou-se a oferta de autocoleta vaginal e uma entrevista com as participantes sobre dados sociodemográficos e impressões da autocoleta. **Resultados:** No total, 1.919 mulheres vivendo com HIV/AIDS com média de 45 anos participaram do estudo. Houve detecção de algum tipo de HPV em 66% (1.267) dos casos. A maioria (71,9%) afirmou preferir a autocoleta à coleta de amostras por profissionais da saúde. Apenas 53,8% das participantes realizaram citologia na periodicidade adequada, conforme recomendação do protocolo. **Conclusão:** Os resultados poderão apoiar a implementação dos testes de biologia molecular para detecção de HPV em mulheres vivendo com HIV/AIDS, incluindo a possibilidade de autocoleta vaginal, promovendo a ampliação do acesso ao rastreamento de câncer do colo do útero.
**Palavras-chave:** Soropositividade para HIV. Papillomavírus humano. Programas de rastreamento. Neoplasias do colo do útero. Serviços de saúde.

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# INTRODUCTION

Cancer of the cervix, or cervical cancer, is one of the main causes of death among women, being one of the most common neoplasms in Brazil. It is estimated that in the 2020-2022 period, there was an annual average of 16,590 cases of this type of cancer, corresponding to 15.4/100 thousand women. In 2017, the mortality rate for cervical cancer was 6.17/100,000, totaling 6,385 deaths in the country[1].

Women living with human immunodeficiency virus/AIDS (WLHA) have a higher frequency of multiple infections, anogenital warts, intraepithelial lesions and anogenital neoplasms resulting from human papillomavirus (HPV) infection, and they are six times more likely to develop cancer than the general population[2,3], requiring special attention from health authorities and health professionals regarding cervical cancer screening in this population.

The cervical cancer screening program in Brazil is opportunistic, taking advantage of the demand for health services for various reasons to offer testing. According to the recommendations of Brazil's National Cancer Institute (INCA) for WLHA, the cytopathological examination should be carried out soon after the beginning of sexual activity, annually after two consecutive normal examinations carried out at a semi-annual interval[4]. Access to screening in the country occurs in a heterogeneous way, with situations in which the person takes the test more frequently than recommended and cases in which women are not up to date with testing, or have never been screened[5-8]. International experiences that employ screening programs of the organized, population-based type, have demonstrated better performance in combating cervical cancer, with a reduction in the incidence and mortality of the disease[9,10].

In addition to changing the screening model adopted, another factor that needs to be reviewed within the scope of the Unified Health System (SUS) is the use of cervical cytology, the only test used for cervical cancer screening in the country since 1970. This diagnostic test has low accuracy in detecting pre-cancerous lesions, is prone to subjective interpretation, does not allow automation and presents a high percentage of false-negative results[11].

New strategies have been developed to increase testing sensitivity and optimize screening for cervical cancer prevention, considering the causal relationship between this type of cancer and oncogenic HPV infection. Molecular tests that amplify viral genetic material (NAAT, nucleic acid amplification test), for example, PCR (polymerase chain reaction) that detects DNA (HPV-DNA) and TMA (transcription-mediated amplification ), are the ones of choice for the diagnosis of HPV in anogenital samples[11-13].

The World Health Organization (WHO) Manual on screening and treatment of pre-cancer cervical lesions for the prevention of cervical cancer recommends, for screening purposes, HPV-DNA detection tests[14]. In this context, self-collection of vaginal samples for HPV study expands access to screening without compromising the quality of test performance, making it possible to offer testing in services that do not have a structure for gynecological care[3,14,15].

# OBJECTIVE

The objective of the present study was to describe the results of a pilot study that evaluated the acceptability of self-collection of vaginal samples and the applicability of offering HPV-DNA tests with self-collection of vaginal samples for WLHA in Brazil.

# METHODS

## Type of study and study population

The study population was taken from the following locations: In the Central-West region, Brasília/DF; in the North region, Manaus/AM; in the South region, Florianópolis/SC and Pelotas/RS; in the Northeast region, Salvador/BA; and in the Southeast region, São Paulo/SP, Juíz de Fora/MG, and Vitória/ES.

The inclusion criteria covered WLHA aged 18 to 64 who had already had sexual intercourse. Exclusion criteria were pregnant women, hysterectomized women or women with gynecological cancer.

## Selection and acquisition of self-collection supplies

Two types of self-collection kits for vaginal samples for HPV detection were available for sale in Brazil at the time the study was designed, and for one of them, importation would be necessary. Therefore, the Coari self-collection kit (Fabricante Kolplast, Brazil), currently available for sale in two different presentations, one dry and the other with preservative liquid, was selected for the pilot as it eliminates the need for import. The presentation with preservative liquid was chosen because it provides greater sample storage stability, considering the distance between the collection centers and the executing laboratory. The kits, before and after collection, were stored at room temperature and without direct exposure to sunlight.

## Work and training process flow

The workflow for organizing the new routine was previously defined with the participating centers (**Figure 1**). The training of professionals was carried out remotely after the arrival of the self-collection kits at the selected health services, due to social isolation measures and the reduction in the flow of people as measures to prevent and contain COVID-19. The training took place at flexible times (aiming at greater professional adherence), lasted around two hours and covered the following topics: general information about HPV and complications in WLHA; flow of work processes; self-collection guidance; methodology for molecular detection of HPV used in the pilot study; and the Brazilian algorithm for case management based on the results of the analyses carried out.

## Sample collection flow

WLHA treated in HIV-specialty healthcare facilities between May/2021 and May/2022 were invited to participate in the pilot study by infectious diseases professionals or other professionals from the multidisciplinary health team involved in the study. The participants received the necessary information about the study, and those who agreed to participate in the study signed an informed consent form. The sample size was calculated by estimating that the proportion of women who would undergo the HPV molecular test but would not have their cytopathological examination up to date would be 50%, culminating in a sample size of 278 women per study site.


**Figure 1.** Flowchart of the pilot study to evaluate the acceptability of self-collection of vaginal samples and the applicability of offering HPV-DNA tests with self-collection of vaginal samples for women living with HIV/AIDS.

## Self-collection of vaginal samples

After signing the informed consent form, the WLHA received the self-collection kits, which were previously evaluated regarding the integrity of the tubes, the presence of preservative liquid in sufficient volume and the condition of the plastic packaging with hermetic closure used to store the tubes with self-collected samples. All identified complications were reported to the manufacturer, who replaced the inputs, as requested.

In addition to the self-collection kit, participants received an illustrated guide containing the step-by-step procedure (**Figure 2**) and, in case of doubt, they also received guidance from health professionals or study researchers. Self-collection was carried out in a private place (bathroom or private room with sink) and without supervision. Intercurrences during self-collections were reported to professionals and, when necessary, a new self-collection kit was made available. The self-collected samples were identified by the assistant professional according to the code standardized in the study. Samples were stored at room temperature until sent to the test laboratory – the Molecular Biology, Microbiology and Serology Laboratory of the Universidade Federal de Santa Catarina (LBMMS/UFSC).

The shipment of the samples from collection centers to LBMMS/UFSC included a carrier specialized in biological sample logistics. Self-collected samples were subjected to DNA extraction using the ReliaPrep™ Blood gDNA Miniprep System kit (Promega, USA), according to the manufacturer's instructions. The Anyplex™ II HPV28 Detection kit (Seegene, Seoul, South Korea) was used for the qualitative detection of HPV genetic material, discriminating the results into 19 high-risk genotypes (16, 18, 26, 31, 33, 35, 39, 45, 51, 52, 53, 56, 58, 59, 66, 68, 69, 73 and 82) and nine low risk (6, 11, 40, 42, 43, 44, 54, 61 and 70), in addition to internal control of the reaction (endogenous human gene). Amplification was performed in the CFX96 real-time thermocycler (Bio-Rad, Hercules, CA, USA), and the reaction results were analyzed in the Seegene Viewer software. The reports issued by the executing laboratory were sent electronically to all health services.

## Interviews

After self-collection of vaginal samples, the participants underwent an interview containing questions about sociodemographic aspects (age, race/color, reading and writing ability, education, income, marital status), impressions about the self-collection process

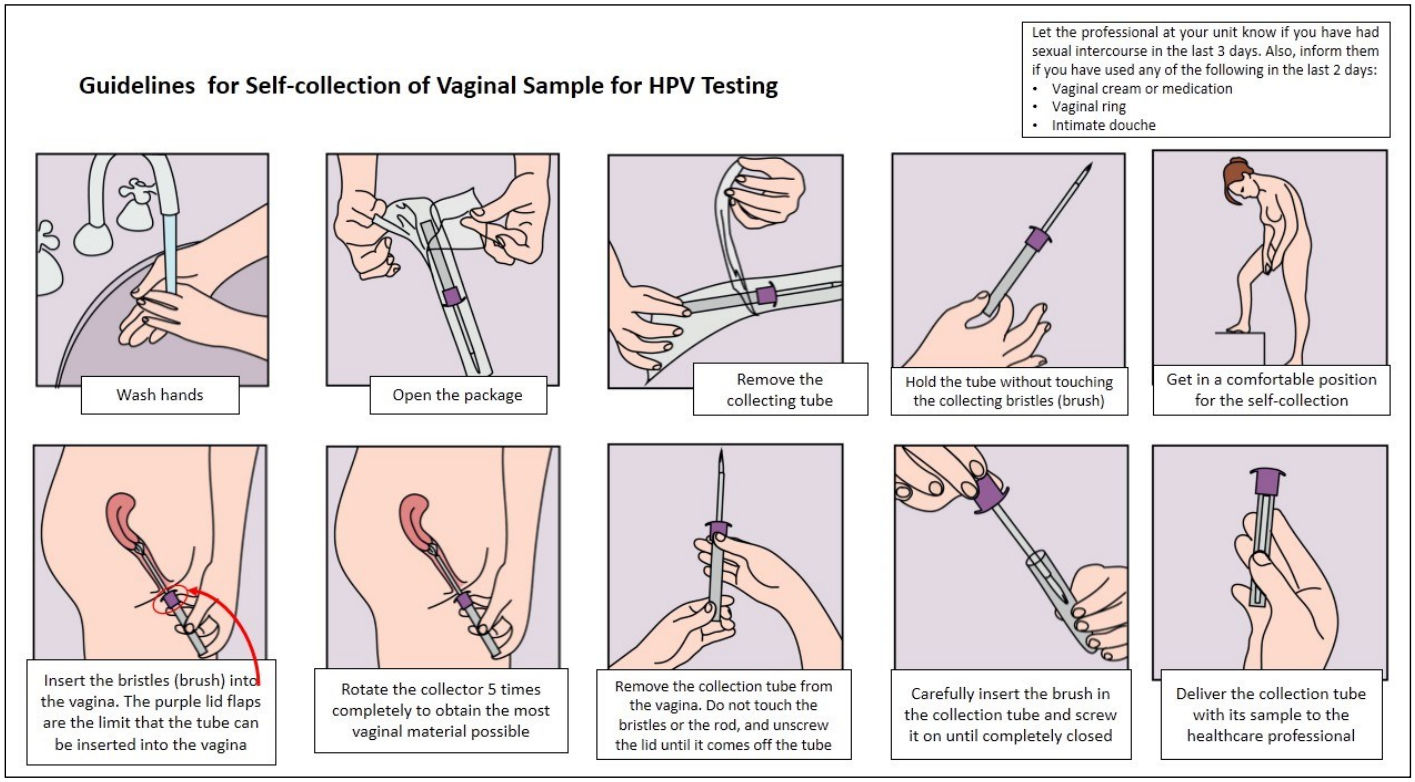


**Figure 2.** Illustrated guide containing the step-by-step procedure for self-collection of vaginal sample for HPV-DNA determinationTransport of samples and execution of tests.

(ease in interpreting the instructions, pain when performing self-collection, perception of comfort, ease of self-collection, preference for self-collection or collection by a healthcare professional). Questions were also asked regarding the performance of the cytopathological examination in relation to its frequency, the result of the last test, when carried out, and the perception regarding the greater risk of WLHA developing cervical cancer. Those who refused to carry out self-collection responded to a questionnaire with the reasons for their refusal. The answers were entered by the interviewer into an online Google Forms form, using a tablet.

## Data analysis

Categorical data related to complications with self-collection tubes and information obtained from questionnaires carried out with participants were presented descriptively using frequencies, and numerical variables, using mean and standard deviation. The analyses were carried out using the Statistical Package for the Social Sciences (IBM SPSS for Windows), version 25.0.

# RESULTS

From May 2021 to May 2022, 2,069 WLHA were invited to participate in the study, of which 1,919 (92.8%) accepted the invitation. Of the total of 150 refusals, 76 (50.7%) claimed lack of time, 18 (12.0%) did not accept self-collection, 18 (12.0%) stated they were not interested in the HPV test, 17 (11.3%) declared that they were undergoing gynecological monitoring, and 21 (14.0%) stated other reasons.

Among the WLHA who agreed to participate in the study, the mean age was 45±11 years. Regarding race/color, 811 (42.3%) were brown, 594 (31.1%) white and 469 (24.4%) black. The majority of participants (1,833, 95.5%) declared that they knew how to read and write; 679 (35.4%) had a primary education level (complete or incomplete), while 637 (33.2%) had a secondary education level (complete). Of the total, 446 (around 23%) said they did not work or have another source of income. Of the women who reported working, almost half (923, 48.1%) had a monthly income equal to or less than the minimum wage (R$ 1,412.00 – $ 260,00). Furthermore, 904 (47.1%) stated that they lived with their husband and/or partner (**Table 1**).

Regarding the cytopathological examination, 47 (2.4%) reported never having had the test before, and 886 (46.2%) did not remember when they last had the test or if they had it more than a year ago. When asked whether they considered that WLHA would have a greater risk of developing cervical cancer, 1,094 (57%) did not believe that HIV increased the risk of this cancer in women or were unable to respond (**Table 1**).

In total, therefore, 1,919 samples were collected, corresponding to an average of 240 samples/center. A total of 238 incidents related to the self-collection kit were recorded, including: tube cracks, tube cap cracks, insufficient volume of preservative liquid and evaporation of preservative liquid during the tube's storage time before collection. Regarding plastic packaging with hermetic closure, 199 incidents were reported related to damaged closure (**Table 2**).

The storage period of the samples at room temperature in the collection centers ranged from 2 to 120 days, with an average of 60 days. The shortest storage time was observed at the service located

**Table 1.** Characterization of women living with HIV/AIDS who participated in the pilot study on self-collection of vaginal sample for HPV-DNA testing in Brazil.

| **Age** | **Years** |
|---|---|
| Mean±SD | 45±11 |
| **Race/Color**[a] | **% (n)** |
| Brown | 42.3 (811) |
| White | 31.1 (594) |
| Black | 24.4 (469) |
| Yellow | 1.4 (26) |
| Indigenous | 0.5 (9) |
| Ignored | 0.5 (10) |
| **Know how to read and write?** | **% (n)** |
| Yes | 95.5 (1,833) |
| No or can only sign name | 4.5 (86) |
| **Education** | **% (n)** |
| Primary (complete or incomplete) | 35.4 (679) |
| Secondary (incomplete) | 8.2 (158) |
| Secondary (complete) | 33.2 (637) |
| Technical education | 3.7 (71) |
| Undergraduate school | 10.7 (205) |
| Graduate school | 4.3 (83) |
| Ignored | 4.2 (86) |
| **In the last month, did you work or have another source of income?** | **% (n)** |
| Yes | 76.8 (1,473) |
| No | 23.2 (446) |
| **Last month's income in minimum wage** | **% (n)** |
| ≤1 | 48.1 (923) |
| >1≤3 | 22.3 (428) |
| >3 | 5.0 (96) |
| Ignored | 24.6 (472) |
| **Live with husband or partner?** | **% (n)** |
| Yes | 47.1 (904) |
| No (Single) | 29.8 (571) |
| No (Separated/Divorced) | 15.0 (288) |
| No (Widowed) | 8.1 (156) |
| **When did you have your last pre-cancer exam (cytopathological exam)?** | **% (n)** |
| ≤1 year | 53.8 (1,033) |
| >1≤2 years | 17.2 (331) |
| >2≤5 years | 9.8 (188) |
| >5≤10 years | 2.2 (42) |
| >10 years | 1.2 (23) |
| Don't remember | 13.3 (255) |
| Never | 2.4 (47) |
| **Do you have the results of the pre-cancer exam (cytopathological exam)?** | **% (n)** |
| Yes | 62.2 (1,193) |
| No | 37.8 (726) |
| **Do you consider that WLHA have an increased risk of developing cervical cancer?** | **% (n)** |
| Yes | 43.0 (825) |
| No | 24.9 (477) |
| Don't know | 32.2 (617) |

SD: standard deviation; WLHA: women living with HIV/AIDS; [a]Self-declared.

in the same city as LBMMS/UFSC (testing laboratory), and the longest time was due to a problem locating the sample stored in the service. After receiving the samples by LBMMS/UFSC, the release of the result for electronic consultation by the clinical professional took up to five business days. The importance of a reduced time between sample collection and result release is highlighted, aiming for an early diagnosis and timely clinical intervention. However, given the budgetary limitations of the pilot study, the samples from each site had to be transported all at once, culminating in this high average storage time of 60 days. Therefore, in the context of HPV-DNA testing being implemented in public health, the costs of sample transportation must be carefully evaluated to ensure a short period of time between sample collection and the delivery to the testing laboratory.

During the transport of the samples, in situations where the health services kept the tubes in a horizontal position in the container, the airtight plastic packaging used was essentially for preventing leakage and avoiding contamination between the samples.

In general, the samples showed good stability, with only five (0.3%) considered invalid; the remaining 1,914 (99.7%) had valid results. Of these 1,914 samples with valid results, in 1,270 (66.35%) at least 1 of the 28 viral types of HPV evaluated was detected, ranging from 1 to 12 viral types in the same sample. In more than half of the samples with valid results (1,049 / 54.81%) there was detection of at least one high-risk HPV viral type.

Regarding the impression regarding the self-collection process, 1,863 (97.1%) considered that the instructions on the leaflet were easy to understand. Only 156 (8.1%) of participants reported pain during self-collection, and 1,799 (93.8%) said it was easy to perform the procedure. Furthermore, 1,622 (84.5%) reported that they felt comfortable carrying out self-collection and that they would recommend it to someone else. Among those who reported discomfort, 269 (14.0%) reported that they would recommend the exam. Regarding the collection strategy, 1,379 (71.9%) reported preferring self-collection; 347 (18.1%) reported having no preference, and 169 (8.8%) stated they preferred collection carried out by a health care professional (**Table 3**).

## DISCUSSION

The present pilot study evaluated the acceptability of self-collection of vaginal samples and the applicability of offering HPV-DNA tests for WLHA in Brazil involved eight HIV-specialty healthcare facilities, located in all regions of the country, and one reference laboratory. Of the total WLHA participants (1,919), 2.4% of women had never had a cytopathological test before, and 46.2% of WLHA did not remember the last time they had the test or if they had taken it more than a year ago, longer than that recommended by INCA for repeat testing in WLHA[4].

Regarding the type of collection, more than 70% of participants claimed to prefer vaginal self-collection rather than sampling by a healthcare professional. Several studies have demonstrated that self-collection of vaginal samples presents similar performance to that performed by health professionals for HPV-DNA tests and that it has high levels of acceptability[3,14–18], consisting of an important strategy for expanding access to testing. The pilot study demonstrated excellent performance of the HPV-DNA tests, with only five (0.3%) invalid samples. The detection of some type of HPV

**Table 2.** *General data of pilot study of self-collection of vaginal sample by women living with HIV/AIDS for determination of HPV-DNA in Brazil.*

| Region | Municipality/ Federative unit | Incident: self-collection kit[a] | Incident: plastic packaging[b] | Number of self-collected samples | Invalid samples | Valid results | Samples with HPV detection (%) | Samples with high-risk HPV detection (%) |
|---|---|---|---|---|---|---|---|---|
| **Southeast** | São Paulo/SP | 65 | 2 | 284 | 0 | 284 | 128 (45.07) | 106 (37.32) |
| | Vitória/ES | 13 | 0 | 207 | 0 | 207 | 145 (70.05) | 129 (62.32) |
| | Juiz de Fora/MG | 27 | 48 | 201 | 1 | 200 | 148 (74.00) | 122 (61.00) |
| **South** | Florianópolis/SC | 14 | 0 | 86 | 0 | 86 | 50 (58.14) | 38 (44.19) |
| | Pelotas/RS | 37 | 84 | 280 | 2 | 278 | 201 (72.30) | 167 (60.07) |
| **Central-West** | Brasília/DF | 50 | 0 | 273 | 1 | 272 | 176 (64.71) | 129 (47.43) |
| **Northeast** | Salvador/BA | 22 | 65 | 293 | 0 | 293 | 186 (63.48) | 158 (53.92) |
| **North** | Manaus/AM | 10 | 0 | 295 | 1 | 294 | 236 (80.27) | 200 (68.03) |
| **TOTAL** | | **238** | **199** | **1,919** | **5** | **1,914** | **1,270 (66.35)** | **1,049 (54.81)** |

[a]Tube cracks, tube cap cracks, insufficient volume of preservative liquid and evaporation of preservative liquid during tube storage time before sample collection; [b]Damaged clasp.

**Table 3.** *Impressions from self-collection of vaginal samples for HPV-DNA detection by women living with HIV/AIDS who participated in the pilot study.*

| Was it easy to understand the leaflet instructions on how to self-collect the sample? | % (n) |
|---|---|
| Yes | 97.1 (1,863) |
| No | 2.1 (41) |
| Ignored | 0.4 (8) |
| Don't know | 0.4 (7) |
| **Did you feel pain when carrying out self-collection?** | **% (n)** |
| No | 91.6 (1,757) |
| Yes | 156 (8.1%) |
| Don't know | 5 (0.3%) |
| Ignored | 1 (0.1%) |
| **How did you feel when self-collecting?** | **% (n)** |
| Comfortable and would recommend it to someone else | 84.5 (1,622) |
| Uncomfortable, but I would do it again | 14.0 (269) |
| Comfortable, but wouldn't recommend it to anyone else | 0.9 (18) |
| Uncomfortable and wouldn't do it again | 0.5 (10) |
| **Do you prefer self-collection or collection by a health care professional?** | **% (n)** |
| Self-collection | 71.9 (1,379) |
| Whatever | 18.1 (347) |
| Collection by a health care professional | 8.8 (169) |
| Ignored | 0.7 (14) |
| Don't know | 0.5 (10) |
| **How difficult was it for you to self-collect?** | **% (n)** |
| Very easy | 32.9 (631) |
| Easy | 60.9 (1,168) |
| More or less difficult | 4.8 (92) |
| Difficult | 0.9 (18) |
| Very difficult | 0.5 (10) |

occurred in 66% of cases, ranging from 1 to 12 viral types in the same sample. Similar positivity was found in a project conducted in the United States, in which 62% of WLHA samples revealed at least one type of HPV[19].

Randomized studies supported the establishment of protocols that employ molecular tests for the detection of HPV to replace cervical cytology in several countries[11,13,20-23]. In Brazil, the Brazilian Association of Pathology of the Lower Genital Tract and Colposcopy recommends the use of HPV-DNA tests since 2018[24]; however, these tests are not yet available within the scope of the SUS. Teixeira et al. [25] demonstrated that molecular biology detection is advantageous and applicable in Brazil. The authors showed that replacing the opportunistic cervical cancer screening program with cervical cytology with an organized screening program, with HPV-DNA detection targeted at all eligible women residing in Indaiatuba (SP), made it possible to detect more cases of cervical cancer, 67% of which are at a very early stage (microinvasive carcinoma), providing opportunities for early diagnosis in up to ten years.

Another important benefit of molecular testing for the detection of HPV-DNA is related to the improvement of the sensitivity of cytology for identifying a malignant lesion when there is prior knowledge of the existence of HPV infection, as demonstrated by Martins *et al*., who observed an increase from 60.0 to 86.7% in this sensitivity[26]. Early detection of neoplasia leads to lower treatment costs, reduced morbidity and increased number of cure cases[3,4,25,26].

The costs of transporting the samples made it impossible for the reference laboratory to collect them more frequently, which prevented the study participants from receiving their results more quickly. For the study, it was decided to use a tube with preservative liquid, due to the unavailability of data in the country on the stability of dry tubes for storing vaginal samples for a period longer than 72 h. In the GRECOSELF Study analyses, dry tubes were used, which showed good storage stability at room temperature for up to 14 days[27]. This interval would be satisfactory if the tests were carried out in a decentralized manner in laboratories distributed across the five regions of the country. However, in situations where there is a need for centralized testing in a single laboratory, as occurred in the present study, validation of the use of dry tubes with storage for periods longer than 14 days would be essential in Brazil.

The dry tube, unlike the tube with preservative liquid, does not pose a biological risk and expands the possibility of types of sample transport, eliminating the need to hire a transport company specialized in biological samples and thus reducing the total cost of the testing[27]. Furthermore, the use of dry tubes allows health services to send the kit for self-collection at home, even by post. These strategies have favored good adherence to testing and are alternatives to be considered for expanding screening coverage[28].

It is critical to maximize synergies between the HIV/AIDS response and efforts to prevent, diagnose and treat cervical cancer through

vaccination, education, testing and management of HPV infections. HIV programs can play a strategic role in expanding cervical cancer screening services[2], by instituting organized screening and implementing molecular biology screening[3]. HIV/AIDS services are strategic to the dissemination of information about cervical cancer to WLHA, given the proximity to this population. Of the participants in this pilot study, 57% did not consider or were unable to answer whether WLHA had an increased risk of developing cervical cancer. The results of this pilot study highlighted the importance of implementing the test to detect HPV-DNA for cervical cancer screening, including the possibility of self-collection of vaginal samples.

### Strengths

The pilot study covered centers in all regions of the country and was highly acceptable to the WLHA (92.8%) invited to take part, and 66% positivity for some type of HPV was found. The majority (71.9%) of participants preferred self-collection to sample collection by health care professionals. This is an important strategy for expanding access to cervical cancer screening, with testing even in places that do not have a gynecological service and the potential to reach WLHA who have never had cytopathological tests before. The change from opportunistic to organized screening, with the implementation of the test to detect HPV-DNA in the SUS, is in urgent need and must occur gradually, prioritizing populations at increased risk and considering the specificities of the country.

### Limitations

This pilot study only reached WLHA who were already in the health services and who agreed to do sample collection on site, taking advantage of the opportunity for care. Given the need for a brief questionnaire to reduce interview and sample collection time, questions about the acceptability of self-collection of vaginal samples were prioritized. Questions related to care for HIV infection, such as adherence to antiretroviral therapy and the presence of AIDS, were not included. Some services had a reduced flow of patients due to the COVID-19 pandemic, which resulted in the impossibility of reaching the collection target initially established in the study. This limitation did not make the study unfeasible, as the data presented involved a population at greater risk of developing cervical cancer and included services located in all regions of the country, both in capitals and in interior areas, proving to be relevant for the development of national measures and policies to control cervical cancer in Brazil.

## CONCLUSION

This pilot study presented results on the acceptability of self-collection of vaginal samples and the applicability of offering HPV-DNA tests with self-collection of vaginal samples for WLHA in Brazil. The study included centers from all regions of the country, with a high percentage of acceptance of participation by the invited WLHIV (92.8%), 66.35% positivity for some type of HPV and more than half of the valid samples showing detection for some type of high-risk HPV. The majority (71.9%) of participants reported preferring self-collection to sample collection by healthcare professionals. The offering of HPV-DNA testing with self-collection of vaginal samples in WLHA proved to be a powerful strategy for expanding access to cervical cancer screening in Brazil, seeking to achieve the elimination goals recommended by the WHO, a strategy to which the country is a signatory[3]. The pilot study covered all regions of the country, including offering testing even in places that did not have a gynecological service; it also reached WLHA who had never had cytopathological tests or who were not up to date with their testing, in addition to showing high acceptability among the participating WLHA. Thus, it is concluded that the results of the present study may support the implementation of molecular biology tests to detect HPV in WLHA, including the possibility of vaginal self-collection, promoting the expansion of access to cervical cancer screening.

### Ethics committee approval

The study was approved by the Human Research Ethics Committees of: School of Medicine of the Universidade Federal de Pelotas (UFPel), under No. 4.567.941, CAAE 43223521.7.1001.5317; STD/AIDS Reference and Training Center, under No. 4.692.020, CAAE 3223521.7.2002.5375; Hospital Universitário Cassiano Antônio de Moraes of Universidade Federal do Espírito Santo (Hucam/UFES), under No. 4.685.258, CAAE 43223521.7.2004.5071; Universidade Federal de Santa Catarina (UFSC), under No. 4.704.088, CAAE 43223521.7.2001.0121; Faculdade de Ciências Médicas e da Saúde de Juiz de Fora, under No. 4.718.416, CAAE 43223521.7.2009.5103; Doctor Heitor Vieira Dourado Foundation of Tropical Medicine under No. 4.768.641, CAAE 43223521.7.2005.0005; Bahia State Health Department (SESAB), under No. 4.829.852, CAAE 43223521.7.2003.0052; and Foundation for Teaching and Research in Health Sciences /Fepecs/SES/DF, under No. 5.000.655, CAAE 43223521.7.2006.5553.

### Participation of each author

PCG: Conceptualization, Investigation, Methodology, Data curation, Supervision, Writing – original draft. MFS: Conceptualization, Investigation, Methodology, Data curation, Project administration, Resources, Writing – original draft. AEM: Conceptualization, Funding acquisition, Investigation, Methodology, Data curation, Supervision, Writing – original draft. MLB: Conceptualization, Investigation, Methodology, Data curation, Project administration, Resources, Writing – original draft. HMM: Conceptualization, Investigation, Methodology, Data curation, Writing – original draft. GFMP: Conceptualization, Funding acquisition, Writing – review & editing. TR: Investigation, Methodology, Data curation, Writing – review & editing. WP: Investigation, Methodology, Data curation, Writing – review & editing. VMP: Investigation, Methodology, Data curation, Writing – review & editing. MVGL: Investigation, Methodology, Data curation, Writing – review & editing. DCBS: Investigation, Methodology, Data curation, Writing – review & editing. AS: Investigation, Methodology, Data curation, Writing – review & editing. DAS: Investigation, Methodology, Data curation, Writing – review & editing. ALC: Investigation, Methodology, Data curation, Writing – review & editing. MAM: Investigation, Methodology, Data curation, Writing – review & editing. IRZ: Investigation, Methodology, Data curation, Writing – review &

editing. ECO: Investigation, Methodology, Data curation, Writing – review & editing. AGAT: Investigation, Methodology, Data curation, Writing – review & editing. SMM: Investigation, Methodology, Data curation, Writing – review & editing.

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## Conflicts of interest

The author declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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