Infectious Agents and Cancer

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Interoperability of two commercial kits in detecting high oncogenic human papilloma virus and genetic diversity in Cameroon: implications for cervical cancer screening strategies in resource-limited settings

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Abstract

Background Cameroon lacks a national screening algorithm for Human papilloma virus (HPV) infection. In order to standardize HPV screening using molecular detection tools in Cameroon, this study aimed to evaluate the concordance of HPV detection via two multiplex systems and profile the epidemiology of High-risk oncogenic HPV (HR-HPV) circulating locally.

Methods A cross-sectional study was conducted on endocervical samples collected among women in Cameroon. HR-HPV detection and genotyping was done using Abbott and Sacace kits simultaneously. Discordant results were retested using Anyplex II HPV28 kit.

Results Of 364 participants enrolled (median-age: 42 [IQR:34–50] years), overall HR-HPV positivity was 21.4% (78/364) versus 15.4% (56/364) using Abbott and Sacace, respectively. Detection concordance between the test kits was strong (kappa-value = 0.8). Of 22 samples with discordant results, 86.36% (19/22) were further confirmed with Anyplex II HPV28; yielding an overall HR-HPV positivity prevalence of 20.6% (75/364), with 12 genotypes circulating. The most

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prevalent genotypes were HR-HPV_16 (18.8%), HR-HPV_18 (16.0%), HR-HPV_39 (16.0%), and HR-HPV_58 (13.0%). Discrepancy in the detection of different and/or same genotype was more prominent for HPV 18 (6/9). Though Sacace is suitable to further discriminate among genotypes, cost-analysis showed that Abbott was 50.6% cheaper in reagents per test.

Conclusions This study revealed a strong concordance between Abbott and Sacace kits for HR-HPV detection, demonstrating interoperability of these two multiplex systems available locally.

Keywords HPV, Cervical cancer, Molecular detection, Multiplex systems, Cameroon

Introduction

The Human Papillomavirus (HPV) is the most common sexually transmitted infection that can affect the skin, genital area, oral cavity and oropharynx [1]. Most people will be infected at some point without symptoms, and the immune system usually clears the infection [1, 2]. However, a persistent infection with high-risk oncogenic HPV (HR-HPV) can lead to abnormal cells and eventually cancer, notably cervical cancer [3–5]. Factors that can increase the risk of HPV persistence include the type of HPV, immune status, other sexually transmitted infections, young age at first pregnancy, hormonal contraceptive use, smoking, and the number of pregnancies and deliveries [3, 4].

Historically, the Pap smear was the primary method used to diagnose cervical cancer. However, in recent years, HPV DNA assays have emerged as superior screening tools [6] and are now recommended by many leading health organizations for primary cervical cancer screening [7]. With an estimated 604,127 new cervical cancer cases diagnosed annually in the world, cervical cancer is the 4th leading cause of female cancer globally and 2nd most common female cancer in women aged 15 to 44 years [8]. In Cameroon, estimates indicate that each year, about 2,770 women are diagnosed with cervical cancer, and 1,787 die from the disease [8]. Cognizance of the morbidity and mortality of HPV driven cancers, the World Health Organization (WHO) has established ambitious targets for cervical cancer elimination by 2030. This includes the vaccination of 90% of girls by age 15 (ideally before the first sexual intercourse), the screening of 70% of adult women using HPV DNA tests, the treatment of 90% of women with pre-cancer and the management of 90% of women with invasive cancer [9]. Cameroon has taken some steps to address cancer control, including establishing a national committee, national cancer control plans for 2003–2007 and 2006–2010, and a strategic plan for cervical cancer 2015–2020 [10, 11]. Despite these interventions, Cameroon falls short of the WHO's elimination targets, with HPV screening coverage significantly below the recommended levels [12]. The country, like the vast majority of African countries, does not have a national cervical cancer screening program. The sporadic nature of screening efforts, primarily carried out by civil society organizations, lacks the systematic approach needed for effective cancer control. The WHO AFRO region in its publication "Status of the Cervical Cancer Elimination Initiative in WHO African Region" recommended that existing multiplex analyzers for molecular testing (TB, HIV, COVID-19, etc.) be leveraged to improve HPV testing coverage [12]. With molecular testing for HPV nucleic acids increasingly taking the place of cytology in cervical cancer screening, over 200 HPV tests are now commercially available worldwide, employing various technologies and targeting different HPV genotypes [13]. Some tests provide complete genotyping, identifying each HPV type separately, while others offer partial, extended, or no genotyping at all [13]. However, only a limited number of these HPV tests commercially available have been validated for cervical cancer prevention based on internationally recognized standards [13]. In effect, the 2023 global inventory of commercial molecular tests for HPVs showed that of the over 250 commercial HPV detection tests available globally, about 50%-79% of these HPV tests did not have sufficient published evidence or any peer-reviewed publications regarding their analytical or clinical performance quality [13].

Despite the wide range of HPV tests available on the market and the screening programmes implemented in other countries, Cameroon specifically lacks standardized guidelines and algorithms, and access to testing services remains challenging. Achieving global and regional targets for HPV testing therefore poses a significant setback in such context. In the meantime, with the COVID-19 pandemic, some multiplex molecular platforms were deployed for SARS-CoV-2 detection. These molecular platforms are currently underutilized and presents an opportunity to leverage HPV molecular detection and characterization. This research therefore aimed to enhance early detection and characterization capabilities tailored for addressing the critical gap in cervical cancer prevention efforts in Cameroon. We compared results from two molecular assays: Abbott HPV kit using the Abbott m2000rt instrument and Sacace HPV kit using the QuantStudio 7 flex. Our comparison of these kits is driven by the fact that the Abbott (present in reference laboratories for decades now, specifically

for HIV viral load testing) does not provide full genotyping during HPV screening, while the Sacace is the more decentralised across the country, following the wake of the Covid-19 pandemic. We therefore aimed to assess the concordance between these two common platforms using the Abbott genotyping kit (specific to the Abott system) and the Sacace kit (selected for its discriminatory multiplexing genotypic profiling). Our goal was to inform decision-making regarding the development of a pragmatic molecular screening algorithm to facilitate the integration of HR-HPV testing into existing healthcare frameworks, ultimately contributing to improved cervical cancer control strategies locally.

Methods

Study design, setting and duration

We conducted a descriptive cross-sectional study with an analytical focus on endocervical samples collected from females in the cosmopolitan cities of Centre and Littoral regions by random sampling. Samples from two hospitals were included in this study, that is, the Gynaeco- Obstetric and Pediatric Hospital of Yaounde (GOPHY) and the Gynaeco- Obstetric and Pediatric Hospital of Douala (GOPHD), while laboratory investigations took place in the Chantal BIYA International Reference Center for research on HIV/AIDS prevention and care (CIRCB's). The GOPHY and GOPHD, Cameroon, are specialized healthcare facilities dedicated to women's and children's health, located in the political and economic capitals for accessible service delivery, respectively. CIRCB on the other hand, is clinical research establishment under the Ministry of Public Health, located in Yaounde. The study duration lasted for six months (06), from June to November 2023.

Study population and sample size determination

Our samples consisted of swab samples collected from women aged 18 years and above, who attended the GOPHY and GOPHD for cervicovaginal screening between Avril to November 2023. According to statistics from IACR, in 2023, the prevalence of HPV in Cameroon is 20.9% [8]. Using this prevalence, we determined our minimum sample size using the Cohran's formula [14], a statistical formula commonly used for calculating the minimum sample size in descriptive studies as follows;

$$\mathbf{N} = (\mathbf{Z}_{\alpha})^{2}\mathbf{p}\,(\mathbf{1}-\mathbf{p})\,/\alpha^{2}$$

where N = The minimum size; p = The prevalence of in 2023 (20.9% or 0.209); α = the accepted margin of error at 5%; and Zα = the reduced deviation (with Zα = 1.96).

Using this formula, we were expected to select a minimum of 254 participants.

Inclusion criteria and enrollment

Participants were randomly and consecutively enrolled from two hospitals based on the following inclusion criteria: (a) Women aged 18 years and above who sought cervicovaginal smear examination/screening at GOPHY and GOPHD between Avril to November 2023, (b) Eligible participants who read, understood the research information (scope, benefits, and possible inconveniences), and accepted to provide consent were consecutively recruited by the study team. Non-inclusion was based on the inability/unwillingness to provide endocervical samples. Also, women who had undergone hysterectomy or cervicectomy, as well as those hospitalized with serious medical conditions were not included.

Data collection procedure

All prospective participants were administered semi-structured questionnaires to collect sociodemographic (age, area of residence, education level) and clinical data (presence or absence of lesions/abnormal vagina discharges, HIV infection status, sexual behaviour and number of partners in the last 12 months, and HPV vaccination status were collected) of women aged 18 years and above who sought cervicovaginal smear examination/screening at GOPHY and GOPHD. Consenting participants were then led to the sample collection room where cervical samples were collected using the Abbott Cervi-Collect Specimen Collection Kit, transported and stored in PreservCyt solution in strict compliance with the Standard Operating Procedure for collection and storage of cervical-vaginal swab specimens as outlined in the Manual of Procedures version 2.8.4 of the GAPPS (Global Alliance for Project Performance standards). Upon collection, all study samples were transferred to sample cryo-racks and stored at -80 °C freezer, pending the start of molecular processing. Vaginal inflammation was assessed by clinical examination by trained health providers and the presence or absence of vaginal discharge was part of this examination.

Laboratory tests

Laboratory tests were carried out at the Chantal Biya International Reference Centre (CIRCB, http://www.circb.cm/btc_circb/web). HPV Genotyping was performed on endocervical samples using the Abbott real-time HR-HPV PCR kit. Viral extraction (DNA) was carried out using the 400uL protocol on *Abbott m2000 SP* platform according to the manufacturer's instructions [15]. Real-time fluorescence detection for HR-HPV genotypes [HPV 16, 18, and the "other category" of other HR HPV genotypes (which could be 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, and/or 68)] were generated with the use of fluorescent labeled probes if any of the aforementioned was/ were present [16]. Our comparative analysis was

performed using the HPV Genotypes 14 Real-TM Quant kit (Sacace Biotechnologies, Italy) following the manufacturer's instructions on QuantStudio 7 Flex RT PCR platform [17, 18]. An initial DNA extraction was performed from 200 µL of Cervico-vaginal sample using the QIAamp DNA Mini kit (Qiagen, Whitehead Scientific, South Africa) according to the manufacturer's instructions [19]. Each sample then underwent real-time multiplexed amplification leading to the detection of at least one of 14 h-HPV genotypes (HPV-16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, and 68) if present.

HR-HPV genotypic concordance between the Abbott and Sacace assays was determined based on a 5 category of HPV genotypic results revealed. They included HPV 16 only, HPV 18 only, HPV 16 and others, HPV 18 and others, and the HPV other category.

Samples with discordant results were further analysed using Anyplex II HPV 28 genotyping kit (Seegene Inc). The Anyplex II HPV 28 genotyping kit is design to amplify and distinguish 28 HPV genotypes simultaneously in a single reaction. Two sets of primers are used to identify 19 h-HPV and 09 LR-HPV genotypes [20].

Statistical analysis

After collecting, all data were entered into a Microsoft Access database with restricted access using anonymous identifiers, and the quality control of data was ensured by double checking of data entry by a second investigator and then validated by the supervisor. Statistical analyses were performed using SPSS version 20. Categorical variables were compared using Chi-square or Fisher's test as appropriate, while proportion's confidence intervals were determined using the Clopper Pearson Exact method. The measure of agreement between the Abbott RealTime HR HPV and the HPV Genotypes 14 Real-TM Quant assays were calculated using the symmetric measures (Cohen Kappa, k), defined as "None" ($\kappa \leq 0.20$), "Minimal" ($0.21 \leq \kappa \leq 0.39$), "Weak" ($0.40 \leq \kappa \leq 0.59$), "Moderate" ($0.60 \leq \kappa \leq 0.79$), "Strong" ($0.80 \leq \kappa \leq 0.90$), or "Excellent" ($\kappa > 0.90$) [21]. The threshold for statistical significance was set at $p < 0.05$.

Ethics and consent to participate declarations

This study adhered to all the principles outlined in the Helsinki Declaration and received ethical clearance from the Regional Ethics Committee with reference: CE N° 0056 CRERSHC/2023 on March 14, 2023. Administrative approvals were obtained from the 2 clinical sites and from CIRCB. All participants provided a written assent, and anonymity was ensured throughout the study by using codes.

Results

Demographic and socio-economic characteristics of the study participants

In total, 364 participants met our selection criteria and were retained for this study. The median age of the study participants was 41 (IQR; 34–50 years old), (Fig. 1.a). Of these participants, 68.4% (249/364) had normal vagina discharges with no cervical inflammation; 30.8% (112/364) showed mild (15.4%; 56/364) to moderate (15.4%; 56/364) cervical inflammation. Only 0.8% (3/364) had severe cervical inflammation, (Fig. 1.b). Up to 84.9% (309/364) attended at least secondary level of education, 62.1% (226/364) were (or had lived; divorced or widow) in couple relationship, 79.9% (291/364) had their first sexual debut before the age of 20. Concerning Gravida, 59.1% (215/364) have had 2–6 pregnancies.

The prevalence and distribution of HPV in the study population

Of the 364 participants' samples analyzed, 21.4% (78/364) [95%CI; 17.3%- 26.0%] tested positive using the *Abbott* HR-HPV PCR kit, while 15.4% (56/364) [95%CI: 11.8%-19.5%] of the participants tested positive on the *QuantStudio 7 Flex RT PCR* system using the HPV Genotypes 14 Real-TM Quant assay (Sacace kit), (Fig. 2).

General concordance between the *abbott* and sacace assays

The measure of agreement between the results from *Abbott* and Sacace assays was strong [Cohen Kappa, $k = 0.800$ (95%CI; 0.721–0.879), $p < 0.001$] with a positive concordance of 72% (56/78) and a negative concordance of 93% (286/308) (Table 1).

HPV genotypic profile detected using the sacace HR-HPV genotyping kit

Of the existing 14 HR-HPV genotypes, only HPV 31 and HPV 51 were not detected using the *Sacace* kit; revealing 12 genotypes circulating. The most occurring genotypes were HPV 16 [13 (18,8%)], HPV 18 [11 (16.0%)], HPV 39 [11 (16.0%)], and HPV 58 [9 (13.0%)] (Table 2).

HR-HPV genotypes concordance between the *abbott* and sacace assays

Of the 78 HPV positive samples obtained using *Abbott* HPV kit, 5 categories of HPV genotypes that were concordant with those of *Sacace HPV High Risk Typing Real-TM* kit were revealed. They include HPV 16 only, HPV 18 only, HPV 16 and others, HPV 18 and others, and the HPV other category. With the Abbott kit, eleven samples were positive for HR-HPV 16 only, 6/78 for HR-HPV 18 only, 2/78 for HR-HPV 16 and others, 3/78 for HPV 18 and others, and the HR-HPV other category (56/78), (Table 3). Twenty-two of the 78 tested positive with the

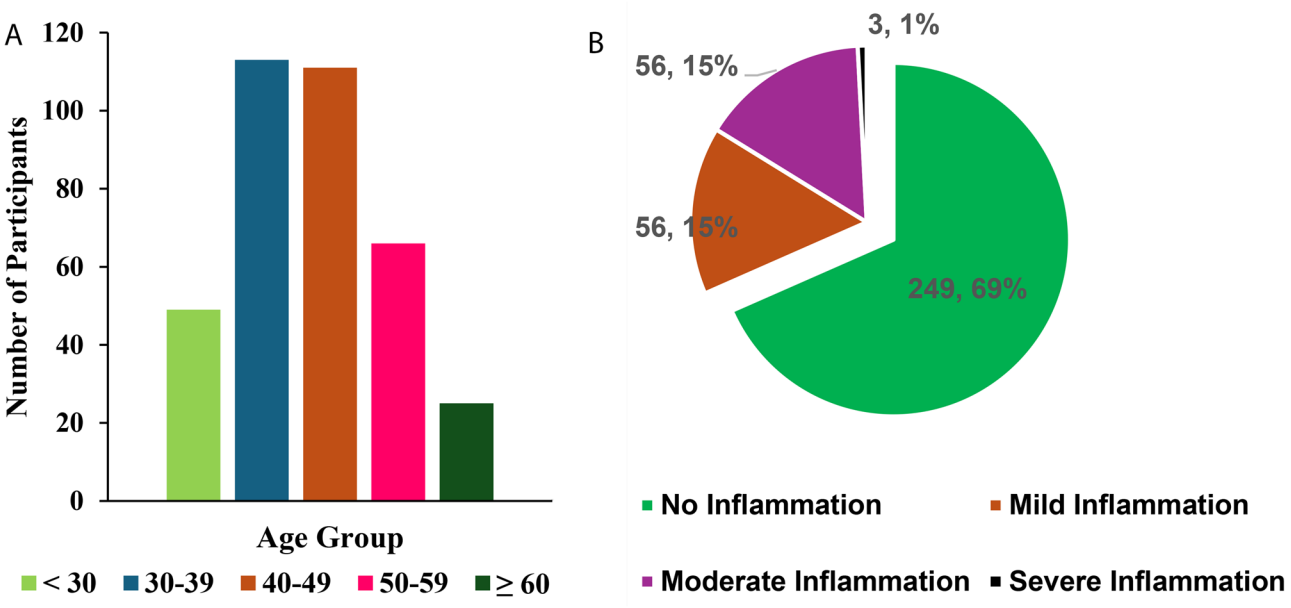

Fig. 1 **a**: Age distribution of participants. **b**: The distribution of participants according to the presence or absence of cervical inflammation

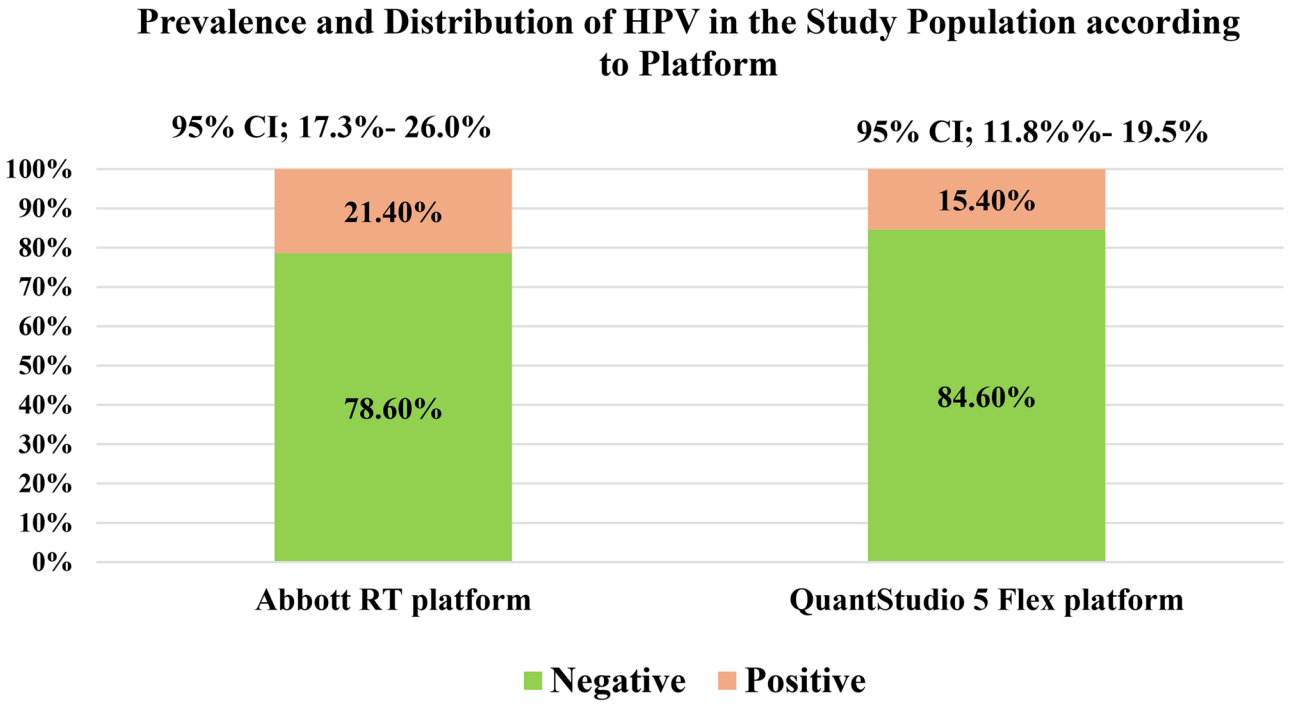

Fig. 2 The Prevalence and distribution of HPV in the study population with the 95% confidence interval (95% CI) for positivity obtained using the clopper pearson exact measure

Abbott kit were negative on the *QuantStudio 7 Flex* using the *Sacace HPV High Risk Typing Real-TM* kit. Table 3 Summarises the results in terms of agreement and disagreement between the two kits on genotypic detection.

All the 22 samples with discordant results were sent for further analysis. Using the *Anyplex II HPV 28 genotyping* (Seegene Inc), only 13.6% (3/22) of these samples retained their undetectability. Table 4: summarises the results of Anyplex II HPV 28 detection assay.

Comparison of costs and parameters – Abbott vs. Sacace HR-HPV assays

Comparative cost analysis shows that the Abbott RealTime HR-HPV assay has a lower reagent cost

Table 1 Concordance between the *abbott* and sacace assays results based on generalised positivity

	***Abbott* Kit**			
Sacace Kit	**HR-HPV Undetected**	**HR-HPV Detected**	**kappa-value (95%CI)**	**p-value**
HR-HPV Undetected	286 (100.0%)	22 (28.2%)	0.8 (0.721–0.879)	< 0.001
HR-HPV Detected	00 (0.0%)	56 (71.8%)		

Kappa between $0.80 \leq \kappa < 1$ indicates strong agreement

Table 2 HR-HPV genotypes detected using *sacace* kit

Genotypes	Frequency
HPV 16	13 (18,8%)
HPV 18	11 (16.0%)
HPV 33	2 (2.9%)
HPV 35	4 (5.8%)
HPV 39	11 (16.0%)
HPV 45	2 (2.9%)
HPV 52	4 (5.8%)
HPV 56	1 (1.4%)
HPV 58	9 (13.0%)
HPV 59	5 (7.2%)
HPV 66	6 (8.7%)
HPV 68	1 (1.4%)

(approximately USD 11.82 per test), compared to the Sacace HR-HPV genotyping kit which is associated with higher reagent costs (approximately USD 23.36 per test). Table 5 highlights a comparative cost analysis between the Abbott and Sacace HR-HPV assays.

Discussion

The WHO has set ambitious targets for cervical cancer elimination by 2030, emphasizing the need for comprehensive vaccination, screening, and treatment strategies. Despite some efforts in Cameroon, including the establishment of national cancer control plans, significant gaps remain in HPV screening coverage and systematic approaches to cervical cancer prevention. This study thus explored the interoperability between two commercial kits already available locally with the potential for improved HPV testing accessibility in the country and beyond.

Table 4 *Anyplex II HPV 28 genotyping* results for discordant samples

	***Anyplex II HPV 28 genotyping* Results**				**p value**
Results Positive for Abbott and negative for Sacace	**Count**	**HPV Undetected n(%)**	**HPV Detected n(%)**	**HPV genotypes Detected**	
HPV 16	1	0 (0.0)	1 (100.0)	16	0.655
HPV 18	4	1 (25.0)	3 (75.0)	18	
HPV 18 and others	2	0 (0.0)	2 (100.0)	18 only	
Others	15	2 (13.3)	13 (86.7)	16, 35, 39, 51, 52, 56, 58, 59, and 70	

This study predominantly included women aged 30 to 49 years. Studies have shown that women between the ages of 35 and 44 years old are more likely to develop cervical cancer than those with ages under 30 and over 50 years old [10, 22]. This demographic trend supports our finding that most participants were within this age group, aligning with the WHO's target of 70% HPV testing for women aged 30 to 45 [9]. Despite the non-existence of a national screening program for HPV testing, sporadic screening efforts by civil society organizations and research institutions have positively impacted HPV awareness and testing scalability. Notably, 69% of participants who underwent cervicovaginal examinations during the study showed no clinical signs of inflammation. This indicates a significant public interest in cervical cancer issues and a proactive approach to seeking HPV screening, even in the absence of discomfort. If a national screening program is developed and implemented, achieving the WHO cervical cancer elimination targets will become feasible.

Although the WHO provides guidelines for cervical cancer prevention, treatment, and control [23], as well as the SDGs target 3.4 National strategy plan for a 1/3 reduction in NCDs related deaths [24], the prevention and control of cervical cancer in Cameroon remain challenging due to limited HPV molecular testing

Table 3 Concordance between the abbott and sacace results according to HPV genotypes

	***Abbott* HPV Results**					
Sacace HPV Results	**HR-HPV 16 (*n* = 11)**	**HR-HPV 18 (*n* = 6)**	**HR-HPV 16 and others (*n* = 2)**	**HR-HPV 18 and others (*n* = 3)**	**Others HR-HPV (*n* = 56)**	**p-value**
# HPV Negative (*n* = 22)	1 (9.1%)	4 (66.7%)	0 (0.0%)	2 (66.7%)	15 (26.8%)	< 0.001
HR-HPV 16 (*n* = 8)	7 (63.6%)	0 (0.0%)	1 (50.0%)	0 (0.0%)	0 (0.0%)	
HR-HPV 18 (*n* = 7)	0 (0.0%)	1 (16.7%)	0 (0.0%)	0 (0.0%)	6 (10.7%)	
HR-HPV 16 and others (*n* = 4)	3 (27.3%)	0 (0.0%)	1 (50.0%)	0 (0.0%)	0 (0.0%)	
HR-HPV 18 and others (*n* = 3)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (5.4%)	
Others HR-HPV (*n* = 34)	0 (0.0%)	1 (16.7%)	0 (0.0%)	1 (33.3%)	32 (57.1%)	

# indicates row with discordant result

Table 5 Comparison of costs and parameters – abbott vs. sacace HR-HPV assays

Parameter	Abbott m2000 – RealTime HR-HPV	QuantStudio™ 5 + Sacace HPV Genotypes 14 Real-TM Quant
System type	Closed system (proprietary)	Open system (real-time PCR)
Test objective	Qualitative detection of HR-HPV	Detection and genotyping of 14 h-HPV types
Clinical sensitivity	≈97–98% (WHO-validated assays)	≈95–100% (according to Sacace IFU and comparative studies)
Clinical specificity	≈98–99% (WHO-validated assays)	≈95–99% (according to IFU and published literature)
Reagent cost (USD/test)	≈ USD 11.82 per test	≈ USD 23.36 per test
Consumables	Proprietary Abbott consumables	Universal PCR consumables
DNA extraction	Integrated automated extraction	Manual / semi-automated extraction
DNA extraction cost	Included	≈ USD 2–4 per test
Operator time	Low	Moderate to high
Equipment	m2000sp + m2000rt	QuantStudio™ 7
Equipment cost	≥ USD 150,000	≈ USD 40,000–60,000
Maintenance	Mandatory service contracts	Local maintenance possible
Multi-pathogen flexibility	Low	High
Platform sharing (mutualization)	Limited	Yes

With reference to WHO and manufacturers' costing, a comparative cost analysis shows that the Abbott RealTime HR-HPV assay has a lower reagent cost (approximately USD 11.82 per test), compared to the Sacace HR-HPV genotyping kit which is associated with higher reagent costs (approximately USD 23.36 per test)

Sources: https://www.amerigoscientific.com/hpv-genotypes-14-real-tm-quant-pcr-kit-item-90255.html

https://cdn.who.int/media/docs/default-source/cervical-cancer/hpv-pricing-slides-2024.pdf?sfvrsn=9a2e29e7_4

opportunities. In the wake of the COVID-19 pandemic, molecular platforms, such as *QuantStudio 7 Flex RT PCR* system, were introduced for SARS-CoV-2 detection, presenting an opportunity to utilize these technologies to scale-up HPV molecular detection and characterization [12].

Our study utilized the *Abbott* molecular system (a WHO-validated system for HPV detection, available in the country even before the COVID-19 pandemic), revealing strong agreement between the *Abbott* and *Sacace kits* (Kappa value of 0.800; CI: 0.721–0.879). This strong agreement present *QuantStudio 7 Flex RT PCR* system as a better alternative molecular system for HR-HPV detection and characterization as current systems (available in Cameroon), such as the *Abbott RT-* PCR, Cobas RT PCR, and Cepheid GeneXpert, while capable of detecting high-risk HPV genotypes, do not provide comprehensive genotype discrimination, which is crucial for understanding the epidemiology of HPV in Cameroon. Although, about 5.2% of the samples analyzed showed discordant results, the observed discordance (5.2% positive and 0.8% negative results demonstrated through Anyplex II HPV 28 genotyping) was primarily due to differences in analytical detection limits. In effect, while the *Sacace genotyping* kit is designed to report insignificant viral concentrations of approximately 10^3 genomic equivalents for 10^5 cells [25], the *Abbott* system detects HPV at a lower threshold [16].

The most frequently occurring HPV genotypes in Cameroon, as identified in our study, were HPV 16, HPV 18, HPV 58, and HPV 39. These findings contrast sharply with a study on HPV genotypes among female sex workers in Cameroon, which reported a high prevalence of HPV infection at 62.1%. The most common types identified in that study were HPV 51 (14%), HPV 53 (12.4%), and HPV 52 (12.2%), with HPV 16 at 5.2% and HPV 18 at 2.8%, suggesting a unique HPV profile in Cameroon [26]. Furthermore, Sosso et al. demonstrated the circulation of multiple HPV genotypes in Cameroon without detailing the relative frequencies of each type identified [27]. Similarly, Mbimenyuy et al., 2023 focused on identifying various high-risk HPV types in normal and abnormal cervical cytology from women in Yaoundé, finding oncogenic HPV types 16, 45, and 18 to be the most prevalent [28]. A 2015 study aimed at determining HPV types present in invasive cervical cancer among women in Cameroon also identified HPV 16, HPV 45, and HPV 18 as the most common genotypes [29]. The discordance in these findings underscores the importance of understanding local HPV epidemiology to inform targeted prevention and treatment strategies in Cameroon. In this light, continuous evaluation is required to allow for adjustments in screening protocols and treatment options based on emerging data and trends in HPV prevalence.

While the concordance between the Abbott and QuantStudio Flex systems is scientifically satisfactory, the cost of using either platform is an important aspect that should not be overlooked. Although the Abbott HR HPV reagents are relatively cheaper (11.82 USD/test) compared to the HPV Genotypes 14 Real-TM Quant reagents (23.36 USD/test), the cost of purchasing and deploying new Abbott PCR systems to regional hospitals is not cost-effective. So far, all regional hospitals in Cameroon have at least one QuantStudio 7 Flex system, which can be leveraged to meet decentralized HPV screening needs in Cameroon. Additionally, the existing QuantStudio 7 Flex systems deployed are currently underutilized, so adding

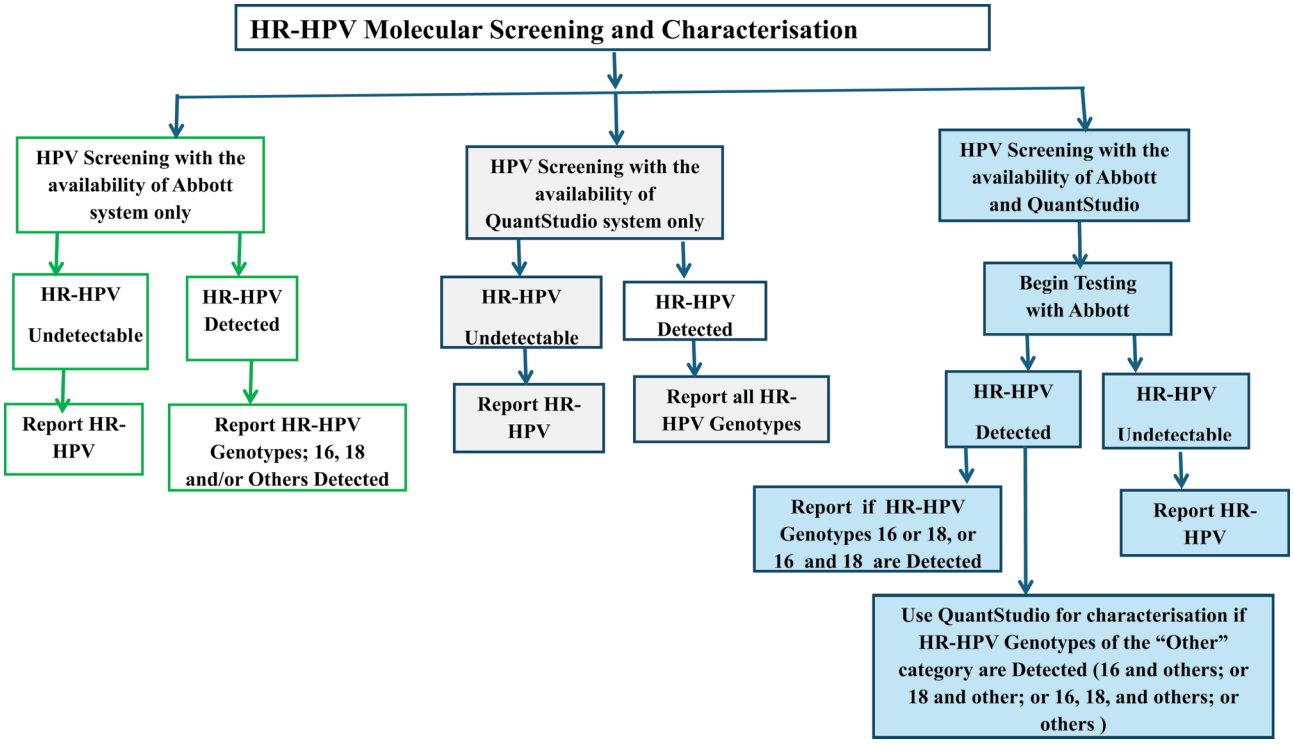

Fig. 3 A proposed algorithm for the molecular detection and characterisation of HR-HPV Genotypes in Cameroon. The Abbott and QuantStudio 7 Flex systems are the two most accessible systems in Cameroon. If available, using the two systems for HR-HPV detection and genotypic profiling will show great promise towards achieving the 2nd and 3rd WHO cervical cancer elimination targets. While the Abbott system is more appropriate for screening because of its higher performance characteristics (sensitivity and specificity), its not suitable for HR-HPV genotypic profiling, compared to QuantStudio 7 Flex ytem. The flow chart gives direction on the preference, usage, and reporting of results depending on the system in use

new molecular systems to the existing ones in a context characterized by a plethora of conflicting challenges is not cost-beneficial. Aside from the cost efficiency of using QuantStudio7 Flex in terms of purchase and maintenance costs, the QuantStudio7 Flex system represent an ideal platform for scaling up HPV testing, genotypic characterization, and epidemiology in a resource-constrained setting like Cameroon, with the capacity of not only discriminating HPV types 16 and 18 as Abbott, but also discriminate HPV types 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, and/or 68. Despite the higher reagent cost for the Sacace HR-HPV kit, the flexibility of the open *QuantStudio™ 7 system*, its ability to support multi-pathogen testing, and its wide availability in sub-Saharan Africa following the COVID-19 pandemic may reduce the overall average cost per test and facilitate the decentralization of HPV screening in low-income settings. Table 5 gives a broader overview of the cost analysis and effectiveness of these two systems under consideration. We have also proposed an algorithm (Fig. 3) for the molecular detection and characterisation of HR-HPV Genotypes in Cameroon. This proposed algorithm takes into account cost effectiveness, resource availability, and performance characteristics of the systems.

As limitations, it is important to note that relying on a single brand of HPV detection kit to compare the performance of another one may lead to conclusions not universally applicable, considering variations often observed within protocols from both manufacturers. The current study evaluated two molecular HPV detection kits available locally employing two different platforms; one widely used globally (Abbott) and the other locally disseminated following Covid-19 pandemic (QuantStudio). To accurately assess the interoperability of multiplex systems as shown in our findings, future research projects/investigations should explore the concordance of these systems using a broader range of available HPV detection kits.

Conclusion

This study revealed a strong concordance between Abbott and QuantStudio7 platforms for HR-HPV detection, presenting an opportunity to enhance and decentralize screening capabilities, improve public health outcomes, and promote equitable access to healthcare HPV detection in Cameroon. The most frequently occurring genotypes identified by both platforms were HPV 16, HPV 18, HPV 58, and HPV 39. Implementing a screening algorithm for HR-HPV that integrates performance,

cost-effectiveness and resource availability will be a game-changer for Cervical cancer screening strategies in Cameroon and countries where these two platforms are currently present.

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Author contributions
Study conception: JF, MCTT, JEG, ENJS, LM, ADN, ACK, YB, SMS, FWM. Data collection and analysis: MCTT, JEG, LM, ENJS, AND, BNFB, KDKK, NNF, ACK, CAC, YB. Manuscript initiation: MCTT, JEG, JF. Revision of manuscript: All authors revised and approved the final manuscript.

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Data availability
Data will be available upon reasonable request from the corresponding author.

Declarations

Ethics and consent to participate
This study adhered to all the principles outlined in the Helsinki Declaration and received ethical clearance from the Regional Ethics Committee with reference: CE N° 0056 CRERSHC/2023 on March 14, 2023. Administrative approvals were obtained from the 2 clinical sites and from CIRCB. All participants provided a written assent, and anonymity was ensured throughout the study by using codes.

Competing interests
The authors declare no competing interests.

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