

Screening Performance and Implementation Determinants of an AI-Assisted Visual Inspection application for Cervical Cancer Screening in Rwanda

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Abstract

Background: Cervical cancer remains a leading cause of preventable cancer death in low-and middle-income countries, where visual inspection with acetic acid (VIA) is widely used but highly dependent on provider expertise. Artificial intelligence (AI) could improve the consistency of VIA interpretation, yet evidence on real-world performance in African primary care settings remains limited. This study evaluated the screening performance of an AI-assisted VIA (AI-VIA) mobile application and identified implementation facilitators and barriers in Rwanda. **Methods:** We conducted a sequential mixed-methods study with an implementation science lens at Kicukiro Health Center, Kigali, Rwanda, from June 18 to July 25, 2025. Expert panel consensus served as the reference standard in the absence of histopathology. Quantitative analysis compared the screening performance of the AI algorithm against clinical expert assessment. Diagnostic accuracy measures such as sensitivity, specificity, positive predictive value and negative predictive value were analyzed, with inter-rater agreement assessed using Cohen's kappa. Qualitative data from a stakeholder focus group discussion were analyzed using the Consolidated Framework for Implementation Research (CFIR) to map implementation determinants. High-priority barriers and facilitators were identified and mapped to the Expert Recommendations for Implementing Change (ERIC) compilation to identify candidate strategies supporting broader implementation. **Results:** Of 251 women analyzed (mean age 35.6 years, SD 6.3), 65.7% had primary education and 88.1% were unemployed. Relative to expert consensus, nurse assessment demonstrated higher screening performance than the AI algorithm, with sensitivity 51.5% (95% CI 33.5–69.2) and specificity 98.2% (95% CI 95.4–99.5) versus sensitivity 33.3% (95% CI 18.0–51.8) and specificity 92.2% (95% CI 87.8–95.4). CFIR analysis identified facilitators including national policy alignment with cervical cancer elimination plan, interoperability, provider enthusiasm for objective decision support, and strategic positioning in the HPV-triage pathway. Critical barriers included algorithm sensitivity requiring dataset expansion, regulatory approvals, connectivity constraints, and concerns about human functions being replaced by AI. **Conclusions:** AI-assisted VIA is feasible as HPV-triage in Rwanda, given high specificity but low sensitivity. Scale-up depends on model optimization with local, histology-confirmed data, interoperability, clear regulation, and workforce engagement.

1. INTRODUCTION

Cervical cancer is preventable, yet it remains a significant global health challenge. According to WHO data from 2022, approximately 660,000 new cases and 350,000 deaths were reported globally, with about 94% of deaths occurring in low- and middle-income countries (LMICs) (1). When detected early and treated promptly, the chances of a full recovery are remarkably high (2). In 2018, 19 of the 20 countries with the highest burden of cervical cancer were in Africa (3), where healthcare infrastructure remains inaccessible for many populations most in need (4). Socioeconomic factors such as poverty, insufficiently equipped healthcare facilities, and low awareness about the preventability and treatability of cervical cancer compound late-stage presentation (5, 6). Additionally, the shortage of pathologists across the continent contributes to misdiagnosis and delayed treatment (7). The International Agency for Research on Cancer estimates that the age-standardized mortality rate from cervical cancer is 21 per 100,000 women in Southern Africa, compared to just 2 per 100,000 women in North America and Western Europe (6).

While Rwanda has made notable progress toward cervical cancer elimination through major investments in HPV vaccination, HPV testing, and screen-and-treat approaches including VIA, cervical cancer remains a major public health challenge. According to Rwanda's Accelerated Plan for Elimination of Cervical Cancer, the estimated incidence is 866 new cases (age-standardized rate of 18.9 cases per 100,000 women) with 609 deaths estimated for 2022 (age-standardized mortality rate 13.8 deaths per 100,000 women). This figure is projected to double to 2,347 cases in 20 years if no effective strategies are implemented (8). A study conducted at a primary healthcare level in Rwanda shows that only 31.8% of healthcare providers (HPs) had a good level of knowledge on cervical cancer screening, and only 17.6% had received proper training on practical screening methods (9).

High-income countries have reduced cervical cancer mortality through cytology (Pap smear) and colposcopy-based programs, but these approaches require laboratory capacity and specialist expertise that are not widely available in many LMIC contexts (10). Visual inspection with acetic acid (VIA) is therefore widely used because it is low-cost, provides immediate results, and enables single-visit screen-and-treat models (11, 12). In Rwanda, national guidance is transitioning to HPV DNA testing as the primary screening test, with VIA used to triage HPV-positive women and determine treatment eligibility. This two-step approach can improve specificity and reduce unnecessary treatment compared with VIA-only screening (8). Nonetheless, VIA interpretation is subjective and varies by provider experience and training, contributing to inter-observer variability and potentially missed or unnecessary referrals and treatments (13). Evidence from AI applications in HPV testing workflows, cytology, and colposcopy suggests that AI can support detection of precancerous lesions with high accuracy (14–16).

Building on this evidence, MednTech¹ developed an AI-assisted VIA (AI-VIA) application to provide real-time decision support during VIA examinations, with the goal of improving consistency of visual interpretation. The app is designed as a frontline screening aid that adds an adjunct layer to reduce subjectivity and support quality assurance. As Rwanda scales HPV-based screening, the app can strengthen VIA triage and follow-up pathways, while remaining adaptable to evolving national workflows. To achieve its full potential, this innovation requires robust data governance frameworks, clear regulations for ethical use, and mechanisms for accountability (17, 18). This work aligns with Rwanda's Accelerated Plan for the Elimination of Cervical Cancer (2024–2027), particularly its efforts to expand access to high-precision screening and timely treatment, contributing to the 90-70-90 targets (8). Rwanda's commitment to this agenda is evidenced by on-the-ground implementation: community health workers are conducting door-to-door campaigns across districts to reach women aged 30–49 for screening (19), including women living with HIV from age 25 (20).

Despite the growth of AI-enabled VIA tools globally (21, 22), evidence on their real-world screening performance and integration within routine clinical workflows in African primary care settings remains limited (23). The goal of this project was to evaluate the application of the app in a real-world context as a critical step to understand and address the implementation determinants. The findings from this project will support its application and assess whether an AI-assisted screening can achieve sustained adoption at scale in Rwanda and other comparable health-system settings. Addressing this implementation gap requires moving beyond diagnostic accuracy alone to examine the organizational, policy, and human factors that enable or constrain adoption.

The Consolidated Framework for Implementation Research (CFIR) provides a structured approach to identifying these multilevel determinants, offering a comprehensive taxonomy of constructs across five domains: Innovation Characteristics, Outer Setting, Inner Setting, Characteristics of Individuals, and Process (24). CFIR has been widely applied in LMIC contexts to guide the introduction of health technologies, including for mHealth interventions in Uganda (25) and the formative design of a mobile VIA screening system in Peru (26). A systematic review of CFIR applications across 21 LMICs found the framework to be largely compatible with resource-constrained settings for understanding culture, stakeholder engagement, and systems-level influences on technology adoption, though some constructs required adaptation depending on research focus and organizational context (27). CFIR can be applied prospectively to identify implementation barriers and facilitators, during implementation to monitor progress, and post-implementation to evaluate outcomes (27). In this context, this pilot study aimed to evaluate the AI-VIA app to strengthen preventive cervical cancer screening services in Rwanda by defining its screening performance and using CFIR to identify multilevel determinants of implementation and inform an evidence-based framework for integration and scale-up.

2. METHODS

2.1 Study Design and Settings

This investigation employed a sequential explanatory mixed-methods design (QUAN → QUAL). A participatory approach was adopted in this context, working with local partners at the Rwanda Biomedical Centre (RBC), Research for Development Rwanda, and the Centre for Impact, Innovation and Capacity Building for Health Information Systems and Nutrition (CIIC-HIN). The quantitative strand assessed the screening performance of the AI-VIA app, while the qualitative strand, conducted after the quantitative phase, explored multi-level determinants of integration in the healthcare system and scale-up, using CFIR. Mixed methods were used to capture the magnitude and meaning of observed changes and to triangulate findings to strengthen validity. This approach generated evidence of screening performance and an understanding of contextual factors influencing adoption and scale-up. Reporting follows the Good Reporting of a Mixed Methods Study (GRAMMS) standard (28).

The study was conducted between June 18 and July 25, 2025 at Kicukiro Health Center. This is a public primary health centre facility in Kicukiro District, Kigali, operating under Rwanda Ministry of Health oversight and managed by Caritas of the Catholic Archdiocese of Kigali and Rwanda Military Hospital, Referral and Teaching Hospital. The facility provides integrated sexual and reproductive health services, including cervical cancer screening, within routine primary care. It hosts a high-volume maternity unit and a fully established HIV clinic, creating sustained contact with women at increased risk of cervical cancer and enabling integration of VIA-based screening within existing services. The center has been an active implementation site for Rwanda's national cervical cancer screening program and is embedded within the national referral network, linking to Masaka District Hospital and Rwanda Military Referral and Teaching Hospital for oncology care.

2.2 The innovation: AI-assisted VIA (AI-VIA) application

The innovation consisted of an AI-VIA mobile-friendly app that supports frontline providers during cervical-cancer screening by capturing cervical images before and after application of 3-5% acetic acid and returning a binary classification (VIA-negative or VIA-positive). The underlying classification algorithm employs a convolutional neural network (CNN) architecture trained on 363 annotated cervical images with labels. Using the app, the healthcare provider collects standardized clinical data across four domains: 1) sociodemographic characteristics (age, education, occupation, marital status); 2) medical history (diabetes, hypertension, HIV, cancer, etc.) ; 3) reproductive history (gravidity, parity, menstrual status, contraceptive use, age at first sexual activity); and 4) lifestyle factors (smoking, alcohol consumption, physical activity). Detailed technical specifications of the AI model and data structure are provided in Appendix 1.

2.3 Quantitative methods

Participants and sampling

Women attending routine cervical-cancer screening were recruited through convenience sampling. As this was a pilot evaluation of screening performance and feasibility, we used a pragmatic target sample of 200 participants informed by feasibility and the expected yield of abnormal VIA findings using national prevalence estimates (precancer 5.9%, invasive cancer 1.7%) (29). This pilot sample was intended to generate preliminary performance estimates and not to provide nationally generalizable estimates. Eligible participants were: 1) Women aged 25–49 years; 2) Sexually active; 3) Able to provide written informed consent prior to screening; and 4) able to understand and respond in Kinyarwanda or English.

We excluded women with one or more of the following criteria: 1) Pregnant at the time of screening (to avoid potential complications or misinterpretations related to pregnancy); 2) with a history of hysterectomy; 3) with previous cervical procedures such as Loop Electrosurgical Excision Procedure (LEEP), cryotherapy, and thermal ablation, or other cervical interventions that may interfere with screening results; 4) having severe or untreated gynecological infections at the time of screening; or 5) with the inability to understand or respond in the available languages (Kinyarwanda or English).

Data collection procedures

Before implementation, three participating nurses completed structured training provided by the first author MF on correct image acquisition², patient consent, data entry, and ethical use of the app. Eligible women were informed of the study purpose before providing written informed consent. Screening followed national VIA protocols. After collecting all relevant sociodemographic and clinical data on the app, participants were taken to the screening room, where a frontline nurse applied acetic acid. The first author (MF) recorded the nurse's visual assessment (positive or negative) and captured two cervical images with the app, both before and after applying the acid. The AI Classification was not disclosed to providers to prevent influence on clinical judgment. This procedure is detailed in Appendix 2.

Because histopathology was not possible within the scope of this study due to financial constraints, the reference standard was medical expert assessment. Two senior Rwandan clinicians, a pathologist and a gynecologist experienced in cervical cancer screening and VIA interpretation, independently reviewed de-identified images and classified each case as VIA-positive or VIA-negative: a board-certified gynecologic oncologist with formal training in colposcopy and cervical cancer screening through the International Gynecologic Cancer Society (IGCS) Global Curriculum and experience supervising VIA within national screening programs, and a pathologist and clinical researcher with over a decade of experience conducting and supervising VIA and colposcopy under NIH-funded studies. A random 15% subset underwent secondary review by VIA-trained midwives for quality assurance. Senior clinician assessment served as the reference standard, while cases with discordant classifications were resolved through a consensus panel including both experts, at least one midwife, and the examining provider.

Data analysis

Continuous variables were summarized as mean (SD) or median (IQR), as appropriate to the distribution and categorical variables as counts and percentages. Screening performance was assessed for three comparisons: (1) AI vs. expert consensus (primary analysis); (2) provider versus expert consensus; (3) AI versus provider.

Confusion matrices were used to visualize misclassification patterns. Then, sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and overall accuracy were computed with 95% confidence intervals, and Cohen's Kappa (κ) was used to assess agreement and κ values were interpreted using Landis and Koch (30). For interpretability, we considered agreement to be high when $\kappa \geq 0.80$. Analyses were performed using *Stata*.

2.4 Qualitative methods

Qualitative inquiry was guided by CFIR to systematically identify determinants influencing feasibility, acceptability, and scale-up of AI-VIA across innovation characteristics, outer setting, inner setting, characteristics of individuals, and process. CFIR was selected over alternative frameworks because of its comprehensive taxonomy of determinants and prior use in LMIC digital health implementations.

Participants and sampling

A purposive sampling strategy was employed to ensure representation from key stakeholder groups. We aimed to recruit 8-10 participants to ensure diverse perspectives on AI adoption and healthcare system integration. They were identified through professional networks and direct invitations. The inclusion criteria were: 1) Healthcare providers such as nurses, general practitioners, gynecologists, oncologists, or community health workers involved in screening; 2) Hospital or health center administrators overseeing service delivery; 3) Researchers or public health professionals working in sexual and reproductive health, digital health, or AI adoption; 4) Policymakers, public health officers, or technical advisors involved in cancer prevention or digital health planning; and 5) Women with lived experience of cervical cancer screening are able to comment on acceptability and feasibility.

We excluded individuals who 1) could not provide informed consent; 2) did not meet any of the inclusion categories; 3) were unavailable on the scheduled date of data collection; or 4) had cognitive or communication limitations preventing meaningful participation.

Data collection

A three-hour in-person focus group discussion was conducted on July 24th, 2025, following completion of the screening phase. The discussion was guided by a CFIR-based facilitation tool covering feasibility, acceptability, barriers and facilitators, recommendations for scale-up, and ethical or operational concerns. Proceedings were conducted primarily in English and occasionally in French, with real-time translation to Kinyarwanda when needed. All sessions were audio-recorded, pseudo-anonymized, and transcribed verbatim.

Data analysis

Qualitative data were analyzed using a hybrid inductive–deductive approach. Transcripts were first open-coded to identify emergent concepts, which were iteratively refined into thematic categories. Themes were then mapped deductively to CFIR domains and categorized as barriers or facilitators. Analytic rigor was enhanced through participant validation, whereby preliminary interpretations were reviewed with participants to confirm accuracy and credibility. All qualitative data were managed and coded using *NVivo* version 15.

Subsequently, constructs were rated for anticipated importance using a 5-point scale (1 = minimal influence to 5 = critical influence on scale-up success) based on the frequency of mention across participant types and the emphasis during discussions. Constructs rated $\geq 4/5$ were prioritized as high-importance for detailed presentation. High-priority barriers and facilitators were then mapped to the Expert Recommendations for Implementing Change (ERIC) (31) compilation to identify potential strategies that could address these determinants in future scale-up efforts. Each selected strategy was contextualized to Rwanda's cervical screening environment using stakeholder-proposed solutions and system-specific considerations from the focus group discussion.

2.5 Integration of findings

Integration occurred during the interpretation stage. Quantitative and qualitative strands were initially analyzed independently, and subsequently brought together to inform an integrated understanding of feasibility, acceptability, and system-level requirements for scale-up. Integration focused on examining how qualitative insights explained real-world considerations surrounding the quantitative screening performance results. This interpretive synthesis guided the development of ERIC-based strategies, ensuring that recommended approaches were grounded in both empirical performance signals and stakeholder-reported determinants.

3. RESULTS

3.1 Quantitative findings

Participant characteristics

Recruitment continued throughout the study period, and 260 women were enrolled, exceeding the minimum pilot target of 200. Out of these 260 women who completed AI-assisted VIA screening, a total of 251 data entries were analyzed. Nine entries (3.5%) were excluded because the corresponding cervical images were deemed inadequate for assessment by the medical experts ($N = 4$), and due to technical data-loss issues during app transmission ($N = 5$). The mean age was 35.64 years ($SD = 6.27$). Most participants had primary education (65.74%), were unemployed (88.05%), and were married (32.67%) or partnered (24.30%). The majority were non-smokers (95.62%), had 3–4 pregnancies (43.43%), and had 3–4 live births (42.63%). Complete characteristics are presented in Table 1.

Screening performance

Three comparisons were conducted to evaluate screening performance. The prevalence of VIA-positive results by medical experts was 13.1% (33/251). Confusion matrices are illustrated in Table 2, and complete diagnostic metrics with 95% confidence intervals (CI) and agreement statistics are presented in Table 3.

3.2 Qualitative findings

Facilitators and barriers influencing integration and scale-up

Qualitative findings ($n = 8$ stakeholders) are based on a stakeholder workshop facilitated by the first author (MF), who was not included as a participant. Stakeholder perspectives on broader AI-VIA app integration and scale-up were analyzed using CFIR. After CFIR coding and importance rating (1–5), we prioritized determinants rated 4 or higher for detailed presentation based on their anticipated influence on national-level implementation and sustained adoption (Table 4). These 17 key determinants are represented across CFIR domains in Fig. 1. All the other CFIR constructs are detailed in Appendix 3. Facilitators and barriers are discussed for selected domains below.

- **Innovation domain.** Key facilitators centered on the app's potential to provide clinical support, address VIA's subjectivity by offering real-time clinical decision support, reduce interpretation errors, and improve consistency across providers. The possibility of capturing and storing images enables second opinions, retrospective review, and skill-sharing between specialists, helping standardize VIA interpretation even where providers have limited training. Providers also described the imaging capability as revealing fine details invisible to the naked eye, supporting more confident decision-making. Additionally, the patient representative noted that showing women their cervix images was seen as empowering patients and helping them understand their results. However, critical barriers emerged around the AI-VIA app's “black-box” nature, which led to variable performance that was difficult to predict. In practice, participants described a “black-box” concern because the app returns a classification without explaining the basis for the output, making unexpected results harder to anticipate and interpret in routine care. Healthcare providers noted performance variation across different conditions, with contradictions likely related to lighting, acetic acid application technique, or other cervical lesions present. Both healthcare providers and the reviewing pathologist highlighted algorithmic differentiation gaps where the AI struggled to differentiate between abnormal cervical conditions that were not acetowhite lesions and normal tissue.

- **Outer Setting domain.** Main facilitators included Rwanda's political system and national digital health strategy supporting digital tools, demonstrating political will and commitment. Alignment with Rwanda's national cervical cancer prevention strategies and plans was seen as a strategic enabler for policy integration. Additionally, stakeholders noted that CBHI already covers cervical cancer screening and precancer treatment, which was viewed as a facilitator for implementation because the app would sit within an existing covered service pathway. However, significant barriers emerged around regulatory requirements, with the app needing Rwanda FDA device oversight and classification before guideline integration and broader implementation. Participants also acknowledged the need for resource mobilization to conduct larger clinical trials and support scale-up activities.
- **Inner Setting Domain.** Facilitators included the importance of integrating the app into Rwanda's electronic medical record (EMR) system to ensure continuity of care, with interoperability viewed as feasible through harmonizing collected data and using application programming interfaces. Moreover, the app's compatibility was perceived as high, fitting naturally into existing workflows as participants noted that VIA itself was already integrated as part of routine primary care processes in these settings, and the imaging function requires minimal extra steps during consultations. The app could also become routine activity similar to sexually transmitted infections testing, though this reflects VIA's established integration rather than characteristics unique to the AI application. Despite these strengths, significant barriers emerged around connectivity challenges in low-resource settings, with suggestions for offline mode functionality to ensure continuity of care.
- **Characteristics of Individuals Domain.** Facilitators centered on participants' recognition of the need for objective decision support given VIA's inherent subjectivity, with many lacking sufficient knowledge or skills to interpret results confidently. Several participants described strong enthusiasm for the app and willingness to champion its scale-up, demonstrating positive attitudes toward AI-assisted screening. However, this is conditional on improving the algorithm through training with locally-sourced data to better reflect local clinical contexts and enhance diagnostic accuracy. At the same time, a significant motivational barrier emerged around fears of AI replacing human roles, with participants emphasizing the need for extensive sensitization to ensure awareness that AI enhances rather than replaces human beings.
- **Process Domain.** Multiple process-related facilitators emerged around strategic planning and implementation approaches. A structured multi-phase implementation roadmap was viewed as facilitating forward planning, including dissemination of pilot findings to diverse stakeholders, resource mobilization for larger clinical trials, and integration into national screening protocols. Implementation strategies were selected to fit the specific context, with approaches including integrating the app to Rwanda's EMR system to support continuity of care. Participants also noted that VIA was already trained in and easily retrainable to using AI-assisted screening. Additionally, Strategic positioning within evolving screening pathways was identified as a key facilitator. Participants emphasized strategic positioning of AI-VIA as a triage tool for HPV-positive women, aligning with WHO's screen-triage-treat approach and Rwanda's transition to HPV-based primary screening (32). Conversely, the need for model enhancement emerged as a critical barrier, with participants emphasizing the necessity to collect more data from confirmed positive cases to improve algorithm accuracy and overall screening performance.

3.3 Integrated findings: strategies for sustained implementation and scale-up

This section presents the mixed-methods integration, where quantitative screening patterns and qualitative CFIR determinants were jointly interpreted to generate actionable strategies. Building on the CFIR-mapped determinants, the CFIR-ERIC Matching Tool (33) was used to identify candidate 2-3 ERIC strategies per emerging determinant, selecting those most likely to enable sustained adoption and scale-up. These strategies were then contextualized to Rwanda's cervical screening environment and aligned with national screening priorities (Table 4). Recommendations span technical, systemic, and human dimensions.

At the innovation level, strategies address AI performance through automated quality monitoring using confidence intervals to flag low-confidence predictions for provider review and cyclical small tests of image capture protocol. At the system level, strategies include formal implementation blueprints mapping AI-VIA onto national screening strategies, multi-stakeholder coalitions spanning cervical cancer programs, digital health, and regulatory bodies, formal commitments from national program leadership defining scale-up timelines, and sustainable funding beyond pilot grants. At the infrastructure level, recommendations target connectivity and workflow constraints through budgeted technical requirements, on-site technical support, centralized data warehousing, and facility-specific workflow tailoring. At the provider level, readiness depends on interactive sessions trialing the app on real cases, champions who address replacement fears and model appropriate use, and job aids demonstrating how AI-VIA standardizes decisions. Finally, at the process level, strategies emphasize the need for phased scale-up with defined evaluation criteria, local consensus discussions positioning AI-VIA within the HPV-VIA screening pathway, advisory boards reviewing progress between phases, and data expert involvement guiding algorithm refinement.

4. DISCUSSION

This study pairs screening performance data with an implementation science approach, addressing a key gap in the AI-VIA evidence base. Overall, our findings show that provider assessments were more closely aligned with expert consensus than outputs from the current AI model. This performance gap reinforces why implementation conditions matter. Stakeholders recognized the potential value of AI as decision support within an HPV-triage pathway, but emphasized that adoption depends on improving algorithm sensitivity, meeting regulatory requirements, ensuring connectivity-resilient workflows, and addressing concerns about role displacement. Policy alignment and feasible EMR integration were seen as key enablers.

Few AI models for visual-inspection cervical screening (VIA or colposcopy) have been prospectively validated within routine clinical workflows, and large-scale effectiveness studies remain scarce (34, 35). We contribute by presenting the first post-deployment evaluation of an AI-VIA app using CFIR. Whereas a Zambian study assessed pre-implementation readiness for AI-based cervical classification (36), our pilot study implementation and analysis examines determinants after deployment, generating contextually grounded insights into barriers and facilitators shaping broader adoption and scale-up. Our findings lead to 4 core observations:

First, the AI performance metrics require contextualization and must be interpreted in light of prevalence effects. Our 13.1% VIA-positive prevalence is slightly higher but comparable to sub-Saharan African screening populations, where positivity typically ranges 11.5%–12.4% according to a meta-analysis (37). It is also within the range reported in Rwanda, where facility-based VIA screening has shown positivity around 18%, although estimates vary by setting and population (38). When prevalence is low, sensitivity estimates become imprecise. Kappa adjusts for chance using marginal totals, so low prevalence increases expected chance agreement and kappa drops even when percent agreement is reasonable (39). This challenge extends beyond our study as a smartphone-based AI-VIA study achieved 75.6% sensitivity with inter-rater reliability of only 0.49, demonstrating the difficulty of establishing ground truth even among experts (40). This issue also surfaced during our focus-group discussion, where participants emphasized that adjudication standards vary considerably and are difficult to define in practice. Furthermore, medical experts in our study adopted a deliberately stringent threshold flagging any suspicious finding as positive for subsequent model refinement, which likely inflated the true-positive denominator against which both AI and providers were measured.

Second, despite these constraints, both AI and providers achieved high NPV, which is clinically significant for triage where ruling out negatives preserves limited treatment resources. Stakeholders accordingly positioned AI-VIA within Rwanda's HPV-based pathway, aligning with WHO recommendations that VIA's primary utility lies in triaging HPV-positive women rather than frontline screening (32). This triage positioning aligns with the multinational PAVE study, which validates deep-learning visual evaluation as triage for HPV-positive women across nine resource-limited countries (34). That said, if our AI-VIA app is to move beyond triage toward frontline screening, sensitivity improvement is essential. This challenge is not unique to our innovation. A systematic review of AI-VIA algorithms found sensitivity ranging from 0.22 to 0.93 and specificity from 0.67 to 0.95, reflecting variable image quality, lighting, acetic acid technique, and limited LMIC training data (41). Hence, achieving reliable performance will require expanded local datasets and context-specific model refinement.

Third, the CFIR findings reveal determinants that converge with and diverge from comparable deployments across sub-Saharan Africa. For instance, Rwanda's favorable policy environment and political commitment to digital health (42), represents an enabling condition often absent elsewhere. In African health-sector AI and digital health, the primary implementation barriers consistently identified are inadequate or absent national policy frameworks, unclear or immature regulatory pathways, including liability and ethics oversight (43, 44). Conversely, connectivity constraints echo continent-wide challenges as only about 28% of sub-Saharan African health facilities have reliable electricity (45). In alignment, the CFIR-based preparatory study on automated visual evaluation and machine learning for digital cervical imaging integrated explicit checks for electricity, Wi-Fi connectivity, and data-flow readiness to enable implementation (36).

Finally, our qualitative findings shed light on psychosocial dynamics warranting strategic attention. Provider enthusiasm coexisting with replacement fears is well-documented. Mixed-methods and scoping reviews confirm that while job-displacement anxiety moderates AI uptake, better knowledge increases intention to use, reinforcing the imperative to frame AI as support rather than substitution (46, 47). Adoption strategy should therefore explicitly message AI as a clinical assistant, ideally championed by opinion leaders, since physicians influenced by recognized peers are approximately three times more likely to adopt clinical technologies (48). Moreover, studies show that patient-facing digital tools enhance agency and shared decisions by expanding access, enabling tailored self-monitoring, delivering health education, and fostering social support (49). This is congruent with our findings, as cervical image visualization is a concrete patient-facing feature that lets women see and understand their own bodies, driving the same empowerment pathway documented across women's digital health interventions.

Taken together, these findings suggest that the near-term value of AI-VIA in Rwanda lies less in replacing clinical judgement than in supporting more consistent VIA interpretation and triage decisions as HPV-based screening and triage pathways continue to scale. Next steps should prioritize prospective evaluations embedded in routine care to assess effectiveness and workflow impact, alongside iterative model refinement using locally generated datasets adjudicated by experts (and histopathology where feasible) to improve sensitivity under real-world imaging conditions. In parallel, implementation readiness will require regulatory clarity, offline-capable workflows, interoperability with EMR systems, and provider training that explicitly positions AI as clinical decision support. With technical performance improvements paired with context-sensitive implementation design, AI-assisted VIA could evolve from a promising pilot into a scalable and trustworthy component of cervical cancer screening pathways in Rwanda and similar settings.

Limitations

This study has some limitations. Expert clinical assessment served as the reference standard in the absence of histopathology, which remains the gold standard for diagnosing cervical precancer (50). Verification bias is also recognized in cervical screening, since standard colposcopy can miss up to 40% of precancers (51). Additionally, the small sample size in the quantitative strand yielded wide confidence intervals precluding definitive performance conclusions. This limitation is not uncommon in early diagnostic accuracy studies as sample size estimation is rarely reported yet critically determines whether estimates are precise enough for clinical decision-

making (52). Moreover, CFIR domain mapping is inherently interpretive, and classification into CFIR constructs may reflect researcher judgement. The first author also led development of the AI-VIA application and served as principal investigator, which may introduce positionality and perceived desirability bias in stakeholder discussions and interpretation. We mitigated this through early engagement of local co-PIs, co-development of the protocol, review of data-collection procedures with implementation experts at Rwanda Biomedical Centre, and validation and refinement of preliminary findings with the broader team and participants. However, workshop participation may have favored stakeholders more engaged with digital health and innovation, and group dynamics may have reduced expression of dissenting views, potentially biasing the balance of reported facilitators and barriers. Finally, qualitative data from one workshop cannot capture how determinants evolve in time. Iterative CFIR assessment more effectively informs strategy tailoring than single-timepoint snapshots: longitudinal applications yield phase-specific determinants, and barrier-derived CFIR-ERIC recommendations show stronger associations with improved care over consecutive years (53).

5. Conclusion

This mixed-methods study demonstrates that AI-assisted VIA screening is feasible and acceptable in Rwandan primary care, while highlighting key considerations for responsible scale up. While diagnostic performance requires refinement through larger locally representative datasets, and more standardized image capture, high negative predictive value supports positioning AI-VIA as triage within HPV-based screening. The CFIR analysis reveals that implementation success hinges more on infrastructure adaptation and workforce engagement than on the technology itself. As cervical cancer elimination efforts accelerate across Africa, translating promising AI tools into sustainable screening programs will require continued attention to context-specific barriers and explicit strategies that position AI as clinical support rather than provider replacement.

Abbreviations

- AI
artificial intelligence
- AI-VIA
artificial intelligence-assisted visual inspection with acetic acid
- CBHI
community-based health insurance
- CI
confidence interval
- CNN
convolutional neural network
- CFIR
Consolidated Framework for Implementation Research
- EMR
electronic medical record
- ERIC
Expert Recommendations for Implementing Change
- FN
false negatives
- FP
false positives
- GRAMMS
Good Reporting of A Mixed Methods Study
- HIV
human immunodeficiency virus
- HPV
human papillomavirus
- IARC
International Agency for Research on Cancer
- LMICs
low- and middle-income countries
- LEEP
loop electrosurgical excision procedure
- mHealth
mobile health
- MoH
Ministry of Health
- NPV
negative predictive value

PPV
positive predictive value
RBC
Rwanda Biomedical Centre
RNEC
Rwanda National Ethics Committee
SD
standard deviation
TN
true negatives
TP
true positives
VIA
visual inspection with acetic acid

Declarations

Ethics approval and consent to participate

Ethical approval for this study was obtained from the Rwanda National Ethics Committee (RNEC 782/2025). All participants provided written informed consent prior to participation. Data were stored securely in accordance with Rwanda's Law No. 058/2021 on Data Protection and Privacy.

Consent for publication

Not applicable.

Availability of data and materials

The datasets generated and/or analysed during the current study are not publicly available because they contain sensitive clinical images and personal health information that are subject to national data-protection regulations and data-sovereignty requirements in Rwanda. The data are available from the corresponding author on reasonable request, subject to approval by relevant national authorities.

Competing interests

MF is the founder and executive director of MednTech, which developed the AI-VIA application evaluated in this study. The authors declare no other competing interests.

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Authors' contributions

MF conceived the study, designed the methodology, coordinated field implementation, and led manuscript drafting. SP and GM contributed to study design and implementation planning. JD led the statistical analysis and contributed to quantitative data interpretation. All authors contributed to manuscript revision, read, and approved the final version.

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Footnotes

1. A nonprofit co-designing digital health solutions to enhance access to preventive healthcare in Africa.

2. Refers to capturing a clear, well lit cervical image with proper focus and appropriate zoom to center the cervix while maintaining image quality.

Tables

Table 1. Participant Characteristics (N = 251)

Variable	Category	N (%)
Age, mean (SD)	35.64 years (6.27)	-
Education Level	Primary	165 (65.74)
	Secondary	45 (17.93)
	None	41 (16.33)
Occupation	Unemployed	221 (88.05)
	Employed	30 (11.95)
Marital Status	Single	42 (16.73)
	Married	82 (32.67)
	Divorced	62 (24.70)
	Partnered	61 (24.30)
	Widowed	4 (1.59)
Smoking Status	Never	240 (95.62)
	Former	6 (2.39)
	Current	5 (1.99)
Alcohol Use	Never	143 (56.97)
	Occasional	92 (36.65)
	Regular	16 (6.37)
Physical Activity	None	143 (56.97)
	Light (1-2 days/week)	56 (22.31)
	Moderate (3-4 days/week)	34 (13.55)
	Active (5 days/week)	14 (5.58)
	Very active (+5 days/week)	4 (1.59)
Number of Pregnancies	0	5 (1.99)
	1-2	86 (34.26)
	3-4	109 (43.43)
	5+	51 (20.32)
Parity (Live Births)	0	9 (3.59)
	1-2	103 (41.04)
	3-4	107 (42.63)
	5+	32 (12.75)
Menstrual Status	Regular	192 (76.49)
	Irregular	54 (21.51)
	N/A (postmenopausal)	2 (2.0)
Age at First Sexual Activity	< 16 years	41 (16.33)
	16-18 years	84 (33.47)
	> 18 years	126 (50.20)
Contraceptive Use	None	102 (40.64)
	Other	132 (52.59)
	IUD	6 (2.39)
	Oral pills	11 (4.38)

Table 2. Confusion Matrices

2a. Healthcare Provider Assessment vs Expert Assessment

	Expert (+)	Expert (-)	Total
Provider (+)	17	4	21
Provider (-)	16	214	230
Total	33	218	251

$TP = 17$, $TN = 214$, $FP = 4$, $FN = 16$

2b. AI Algorithm vs Expert Assessment

	Expert (+)	Expert (-)	Total
AI (+)	11	17	28
AI (-)	22	201	223
Total	33	218	251

$TP = 11$, $TN = 201$, $FP = 17$, $FN = 22$

2c. AI Algorithm vs Healthcare Provider Assessment

	Provider (+)	Provider (-)	Total
AI (+)	10	18	28
AI (-)	11	212	223
Total	21	230	251

$TP = \text{True Positive}$

$TN = \text{True Negative}$

$FP = \text{False Positive}$

$FN = \text{False Negative}$

Table 3. Screening Performance and Agreement Statistics (Cohen's κ)

(a) Screening Performance Metrics with 95% CI

Rater Pairs	Sensitivity % (95% CI)	Specificity % (95% CI)	PPV % (95% CI)	NPV % (95% CI)
Provider vs Expert	51.5 (33.5–69.2)	98.2 (95.4–99.5)	81.0 (58.1–94.6)	93.0 (88.9–96.0)
AI vs Expert	33.3 (18.0–51.8)	92.2 (87.8–95.4)	39.3 (21.5–59.4)	90.1 (85.4–93.7)
AI vs Provider	47.6 (25.7–70.2)	92.2 (87.9–95.3)	35.7 (18.6–55.9)	95.1 (91.3–97.5)

Note. For Provider vs Expert and AI vs Expert comparisons, expert panel consensus served as the reference standard. For AI vs Provider comparison, provider assessment served as the reference.

CI = Confidence Interval

PPV = Positive Predictive Value

NPV = Negative Predictive Value.

(b) Inter-Rater Agreement Statistics (Cohen's κ)

Rater Pairs	Cohen's κ	Standard Error	95% CI	Interpretation
Provider vs Expert	0.587	0.061	0.467-0.707	Moderate agreement
AI vs Expert	0.273	0.063	0.150-0.396	Fair agreement

Kappa interpretation based on Landis & Koch (1977): $\kappa < 0$ (poor), 0.0–0.20 (slight), 0.21–0.40 (fair), 0.41–0.60 (moderate), 0.61–0.80 (substantial), and 0.81–1.0 (almost perfect) agreement

Table 4. Key CFIR Barriers and Facilitators for AI-VIA Scale-Up and Integration

Domain	CFIR Construct	CFIR Definition	Study-Specific Definition	Determinant	Facilitator	Barrier	Supporting Verbatim
Innovation	Relative Advantage	The innovation is better than other available innovations or current practice.	Perceptions of how AI-VIA compares to standard VIA screening practices	Enhanced diagnostic support	✓		"As you know, the VIA itself is a subjective test and most of our healthcare providers, have not enough knowledge or skills to use or interpret VIA...AI with VIA can help to increase accuracy of VIA, but also improve clinical decision" - Implementation specialist at Rwanda Biomedical Centre (RBC)
				Patient empowerment and engagement	✓		"We could clearly see the small features that were not very well visible with our naked eyes." - Nurse and clinical coordinator
	Complexity	The innovation is complicated, which may be reflected by challenges in defining and measuring its performance.	AI-VIA is complicated as a black-box system with variable and difficult to predict performance	Performance variation across conditions		✓	"The contradictions.. were probably the light, probably the way we apply the acetic acid, probably the other lesions that the client had." - Nurse and clinical coordinator
Outer Settings	Local Conditions	Economic, environmental, political, and/or technological conditions enable the Outer Setting to support implementation and/or delivery of the innovation	Political, technological, and healthcare system conditions that affect AI-VIA implementation and screening access	Political will and commitment	✓		"First of all, I can say that it is a political will, it is aligned with our strategic objectives, and second Rwanda is moving fast. for the digitalization of our system and AI solution is part of this framework of digitalization." Implementation specialist at RBC.
	Policies & Laws	Legislation, regulations, professional group guidelines and recommendations, or accreditation standards support implementation and/or delivery of the innovation	Policy, regulatory requirements and guidelines that support or constrain AI-VIA adoption and integration	Alignment with strategic frameworks and national plans	✓		"The most important facilitator is the environment... the strategic plan, the Mission 2027, the already existing infrastructure in terms of training... and of course in most of the African setting VIA has been
				Device oversight and			

			classification		✓	done for a very long time as a primary tool for screening." - Pathologist and researcher. "Anything related to implementation of any clinical related matter should be also endorsed by RBC and MoH. - Implementation specialist at RBC.
	Financing	Funding from external entities (e.g., grants, reimbursement) is available to implement and/or deliver the innovation	Integration into community-based health insurance system and need for resource mobilization for scale-up	CBHI coverage	✓	"Screening is part of our community based insurance. VIA, Thermal ablation, HP sample collection is part of CBHI." - Implementation specialist at RBC.
				Resource mobilization for scale	✓	"We need to see if we can make grand mobilization to make larger, broader clinical trials" - Implementation specialist at RBC
Inner setting	Structural Characteristics: Information Technology Infrastructure	Technological systems for tele-communication, electronic documentation, and data storage, management, reporting, and analysis support functional performance of the Inner Setting	Technology infrastructure for AI-VIA deployment and health information management	Infrastructure and interoperability	✓	"I think the best way we can ensure and follow up on this tool is to see how we can integrate also this into our EMR system so that images being taken from this application can be linked to our EMR system so that it can be part of continuity of care of our clients." - Implementation specialist at RBC.
				Connectivity limits	✓	"If they can make it work offline... when there is no internet, it will be helpful." - Nurse and clinical coordinator

Individuals - Characteristics	Compatibility	The innovation fits with workflows, systems, and processes	Perceived ease of integrating AI-VIA into existing VIA screening workflows without major disruption	Ease of integration into workflow	✓	"I would say it is the same as when someone comes for STI treatment. It does not take much time, as she mentioned, and if it is accessible to all providers, then it will become like a routine activity." - Head of a community health centre
	Need	The individual(s) has deficits related to survival, well-being, or personal fulfillment, which will be addressed by implementation and/or delivery of the innovation	Healthcare providers need better decision support for subjective VIA interpretation	Reducing VIA subjectivity	✓	"As you know, the VIA itself is a subjective test and most of our healthcare providers, have not enough knowledge or skills to use or interpret VIA." Implementation specialist at RBC.
	Motivation	The individual(s) is committed to fulfilling role	Individual attitudes toward adopting and using AI-VIA	Positive attitudes toward AI-VIA	✓	"For me, I found this AI to be very good, so I would encourage others to use it as well." - Patient representative.
				Fear of replacement		✓ "I appreciated the App and then I would wish it to be validated and to be tested somewhere else on a large population" - Healthcare provider. "A lot of sensitization should be done to make sure we are aware that it's there to enhance, not replace human beings." - Public Health Researcher

Process	Planning	Identify roles and responsibilities, outline specific steps and milestones, and define goals and measures for implementation success in advance.	Development of a structured implementation roadmap that defines sequential milestones from evidence generation to policy adoption, and outlines pathways for regulatory and guideline integration	Multi-phase implementation roadmap	✓	"I think the next step is first publication of findings from this pilot or involving different stakeholders including policymakers, researchers and academicians and different partners and NGOs... Second we need to see if we can make grand mobilization to make larger, broader clinical trials... And third, starting to see the aspect of this product that can be integrated into our protocol guideline." - Implementation specialist at RBC
	Tailoring Strategies	Choose and operationalize implementation strategies to address barriers, leverage facilitators, and fit context.	Implementation strategies tailored to fit local context for AI-VIA broader deployment	Health system integration approach	✓	"I think the best way we can ensure and follow up on this tool is to see how we can integrate also this into our EMR system so that images being taken from this application can be linked to our EMR system." - Implementation specialist at RBC
	Adapting	Modify the innovation and/or the Inner Setting for optimal fit and integration into work processes.	Identification of needed app/AI modifications to optimize innovation performance and fit	Need for model enhancement	✓	"The plan is to go extra mile and be able to collect all these images of positive cases and then use all these different algorithms to be able to train it." - Public Health Researcher
				Strategic positioning in screening pathway	✓	"So I think now the tool can be integrated mostly at VIA triage not VIA screening as we are no longer recommending it. We're recommending HPV as primary screen test and then for those who are HPV positive, it's where we use the VIA." - Implementation specialist at RBC

Table 4. Expert Recommendations for Implementing Change (ERIC) Strategies for Scale-Up and Sustained Implementation

Domain	Emerging theme	ERIC Strategy	Contextual Application
Innovation	Enhanced diagnostic support (F)	Conduct educational meetings	Implement competency-based training for providers on AI-VIA use post-validation and improvement, covering image capture technique, interpretation of AI output within clinical context, and quality assurance criteria.
		Inform local opinion leaders	Position AI-VIA within existing national cervical cancer elimination strategies and HPV-triage screening pathways. Frame the app as addressing documented implementation gaps (subjective VIA interpretation variability, limited provider training) in the triage workflow.
	Patient empowerment and engagement (F)	Involve patients/consumers and family members	Engage women in iterative refinement of visual explanation and counseling approaches around cervical images and results. Include diverse populations to ensure counseling scripts and visual aids are acceptable and comprehensible across different contexts during scale-up.
		Obtain and use patients/consumers and family feedback	Collect structured feedback from women on whether and how visual explanation of cervical images enhances understanding of results and reduces anxiety. Use this feedback to refine counseling protocols to optimize patient experience and treatment uptake.
	Performance variation across conditions (B)	Develop and implement tools for quality monitoring	Implement automated quality filtering using model confidence intervals as decision thresholds. Flag low-confidence predictions for provider review rather than automated triage, and systematically review flagged cases to identify conditions affecting performance and refine protocols.
		Conduct cyclical small tests of change	Pilot targeted improvements to image capture protocol (e.g., standardized lighting, timing, retake procedures) through rapid cycles at research sites before broader rollout. Test whether specific protocol adjustments reduce ambiguity and discordance, then decide adoption based on evidence.
Outer Setting	Political will and commitment (F)	Involve executive boards	Engage national health program leadership in planning next phases (clinical trials, regulatory pathway, guideline integration) through formal governance channels. Present findings in policy language aligned with national cervical cancer elimination targets rather than research terminology.
		Obtain formal commitments	Establish written agreements with national program leadership defining roles and timelines for scale-up phases.
	Alignment with strategic frameworks and national plans (F)	Build a coalition	Bring together representatives from cervical cancer programs, digital health, primary care, and hospitals into a coalition that jointly steers AI-VIA implementation.
		Develop a formal implementation blueprint	Co-write a document explicitly mapping AI-VIA onto national screening strategies and health plans. Describe implementation phases, activities, responsibilities, and indicators. Use this as the reference point when aligning with new partners or making programmatic decisions.
	Device oversight and classification (B)	Create or change credentialing and/or licensure standards	Work with regulatory bodies to establish standards for AI decision-support tools in cervical cancer screening. Define requirements for evidence, competency, procedures, and responsibilities and create a clear regulatory pathway for adoption.
	Resource mobilization for scale (B)	Access new funding	Identify and pursue sustainable funding sources beyond pilot grants to support medium-to long-term implementation.
		Develop resource sharing agreements	Negotiate arrangements where devices, connectivity, or technical support are shared across services or facilities to stretch limited resources and make financing more sustainable.
Inner Setting	Infrastructure and interoperability (F)	Change physical structure and equipment	Plan and finance infrastructure upgrades needed for implementation: appropriate devices, secure storage, and basic network equipment.
		Use data warehousing techniques	Design a central or regional data where images and results from multiple sites can be stored, indexed, and accessed securely to reduce the burden on individual facilities and support integration with national systems.
	Ease of integration into workflow (F)	Tailor strategies	Adapt the detailed steps of how AI-VIA is used in each facility based on local staffing patterns and clinic flow,

			while maintaining core functions and quality standards.
		Promote adaptability	Encourage teams to make small, context-specific organizational adjustments in how they operationalize the app and share successful adaptations across sites.
	Connectivity limits (B)	Fund and contract for clinical innovation	Integrate connectivity and technical requirements directly into budgets and service contracts.
		Provide local technical assistance	Arrange on-site or easily accessible technical support for device configuration, troubleshooting, and digital skills building.
Characteristics of Individuals	Positive attitudes toward AI-VIA (F)	Conduct educational meetings	Organize interactive sessions where providers trial the app on real or sample cases and discuss practical questions.
	Reducing VIA subjectivity (F)	Develop educational materials	After model improvement and validation, produce job aids, posters, or reference materials demonstrating how AI-VIA standardizes decisions and improves consistency.
	Fear of replacement (B)	Identify and prepare champions	Train nurses and clinicians not only in using AI-VIA but also in how to talk about it: emphasizing that AI is a support tool, sharing examples of how it helped them, and modeling appropriate use.
		Conduct educational outreach visits	Send trained champions or implementation team members to visit facilities, observe workflows, and address fears and misconceptions in context.
Process	Strategic positioning in screening pathway (F)	Conduct local consensus discussions	Facilitate discussions with national, district, and facility-level stakeholders to agree on where exactly AI-VIA sits in the HPV-VIA-screening pathway and under what conditions it should be used.
		Conduct local needs assessment	Gather information from providers and managers on uncertainties and bottlenecks in the current screening pathway. Use findings to justify and fine-tune AI-VIA's role and positioning.
	Health system integration approach (F)	Tailor strategies	Choose integration modalities that fit each digital system in place rather than forcing a one-size-fits-all solution.
		Change record systems	Modify clinical records and reporting systems to include a defined space for AI-VIA outputs and images. Prevents results remaining 'in the app only' and integrates the tool into routine documentation.
	Multi-phase implementation roadmap and stakeholder engagement (F)	Stage implementation scale-up	Plan roll-out in successive phases, each with specific objectives and evaluation criteria.
		Use advisory boards and workgroups	Create advisory groups at national or regional level that meet periodically to review progress, interpret implementation data, and advise on adaptations between phases. Include frontline representatives to keep the roadmap grounded in realities on the ground.
	Need for model enhancement (B)	Develop and implement tools for quality monitoring	Define indicators that track model performance and image quality by site and over time.
		Audit and provide feedback	Regularly review these performance and quality data with providers, managers, and regulators. Use audits to discuss reasons behind errors or discordance, and to agree on changes in data collection, thresholds, or workflows.
		Use data experts	Involve data scientists, statisticians, or informatics experts to analyze performance trends, identify patterns and guide technical decisions on retraining, calibration, or algorithm updates.
		Conduct cyclical small tests of change	Test algorithm refinements or data collection changes in selected sites first, monitor impact on performance metrics, and scale improvements based on success.

F: Facilitator ; B: Barrier

Figures

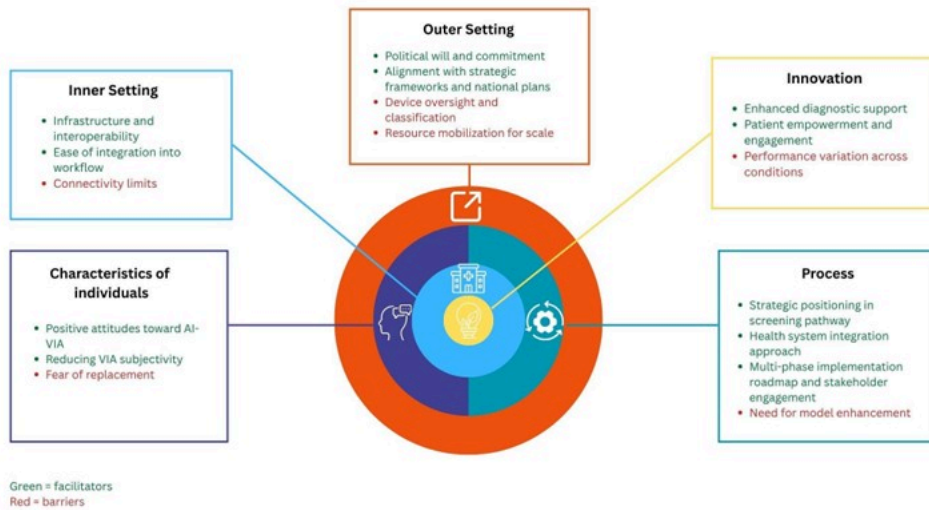


Figure 1

CFIR-mapped determinants for integrating the AI-VIA app into cervical-cancer screening services

Visual structure inspired by Best et al. (2021)

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- [supplementarymaterial.docx](#)
- [Appendix.docx](#)