The Regulation and Quality Improvement Authority

# Report on RQIA Audit, Guidelines and Quality Improvement (QI) Programme 2019/2020 Project: Self-sampling to decrease the DNA rate in people referred to Colposcopy or on follow up for cervical abnormalities

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Assurance, Challenge and Improvement in Health and Social Care

**Context**

The Cellular Pathology Department at Altnagelvin Hospital, Western Health and Social Care Trust is made up of two pathology disciplines; Histopathology and Cytopathology. One of the principle functions of the Cytology laboratory is the provision of cervical Cytology tests (more commonly known as the smear test). Cervical Cytology is the primary cervical screening test in Northern Ireland and it aims to detect abnormalities of the cervix known as Cervical Intraepithelial Neoplasia (CIN).

Women aged between 25 and 49 are invited for screening every three years and women aged between 50 and 64 are invited every five years. When performed routinely, cervical screening can help in the detection and treatment of cervical abnormalities. In Northern Ireland, early detection and treatment of CIN prevents approximately 75% of cervical cancers developing.[1]

Biomedical Scientists in the Cytology laboratory microscopically check cervical Cytology samples for cellular changes. All potentially abnormal cases are referred to a Pathologist for confirmation and management recommendations. The detection of cell changes by Cytology leads to further investigation, and patient referral to a Colposcopy clinic for examination and possible treatment is required.

Patients are usually followed up at approximately six months after treatment to check that treatment has been successful. Women who are referred to Colposcopy and even those who have attended and had treatment have a higher than background risk for high-grade cervical disease and cancer development therefore it is important that they are not lost to follow up.

The Cytology laboratory therefore has a failsafe system in place to follow up this high-risk group and records show that up to 15% of patients do not adhere to management recommendations for referral/follow up by the laboratory, Colposcopy or their General Practitioner (GP).

Many studies have shown that patients who do not attend (DNA) for cervical appointments are more willing to self-collect a vaginal sample for human papillomavirus (HPV) testing to determine their risk of cervical disease [2, 3] and if they test HPV positive (an indication of increased risk) they are more likely to attend for cervical investigation. [4] In a previous pilot study conducted by our own laboratory at the Altnagelvin Cytology Department, self-sampling was offered to women 25-29 years old and 55-64 years old in the general population who didn't attend regular screening. Early results from this study have indicated that cervical screening uptake can be improved by offering self-sampling to under or never screened groups.

The study found that of 1150 invitations sent, 188 (16.3%) took up the self-sampling offer. Of the self-samples that were returned to the laboratory for testing, 37 (19.7%) tested HPV positive and 31 (83.8%) of the positive group attended for their subsequent smear. All of those who had an abnormal smear result attended Colposcopy when referred.

The Cytology laboratory will therefore extend this self-sampling initiative to decrease the DNA rate in people referred to Colposcopy or on follow up for cervical abnormalities. It is anticipated that targeting this high-risk population in order to reduce the DNA rate, will

result in a subsequent reduction in cervical disease and cervical cancer. The Quality Improvement Prototype aims to enable the Cytology laboratory failsafe system to reduce the number of patients who DNA from the current level of 15% to 5% or less by 31 December 2019.

## Background

Cervical screening has contributed significantly to a reduction in cervical cancer incidence and mortality; [5] however, the effectiveness of screening programmes is limited by non-attendance for initial screening tests and the follow-up tests required for patients that have had abnormalities identified and/or treated. Generally non-attenders are at higher risk of cervical cancer; [5] therefore, it is important to explore strategies to encourage this group to attend for cervical appointments. Studies have shown that the main barriers to attending for clinician-based collected samples are concerns regarding discomfort, embarrassment, and low perceived risk of cancer.[6, 7]

In many studies, non-attenders have indicated that self-collection of samples would be a preferable option for them.[2, 3] There is strong consistent evidence that offering self-sampling to non-attenders improves screening participation. Eight randomised controlled trials have reported improvements in participation rates of between 4% and 24% compared to an additional recall letter,[2] and several studies conducted in Europe have shown that offering self-sampling to women could increase screening coverage.[8-11] Three studies that examined adherence to screening follow-up after a positive HPV test and subsequent Colposcopy referral reported high adherence (68–100%).[4] These findings are consistent with the findings of the pilot study conducted by our own laboratory as previously outlined.

Testing for HPV, the main cause of cervical cancer,[12] is becoming the preferred primary cervical screening test owing to its higher sensitivity to detect cervical cancer precursors, (CIN grade 2 or worse and grade 3 or worse [CIN2+, CIN3+]) compared to cervical Cytology.[13] This provides an opportunity to specifically identify the non-attenders who are at risk of cervical cancer by offering women the option of self-collecting a vaginal sample that can be tested for the presence of HPV. Women who test HPV positive have an increased risk of developing cervical lesions that, if left untreated, could lead to cervical pre-cancer and cervical cancer. Furthermore, vaginal self-sampling has undergone extensive research and it has demonstrated a sensitivity to detect cervical disease that is equivalent to that of clinician-collected samples.[8-10, 14]

The Netherlands Cervical Screening Programme introduced HPV primary screening in 2017 and a component of the programme involves offering vaginal self-sampling for HPV detection in under or never screened women. The NHS Cervical Screening Programme is also currently considering the introduction of self-sampling for people who do not attend for cervical screening when the programme moves to HPV primary cervical screening in 2019/20.

This QI prototype is focused on listening to and addressing the needs of patients who require follow up but are not willing to undergo a clinical cervical test without evidence

that it is absolutely necessary. Targeting a high-risk population to reduce the DNA rate will result in subsequent reduction in cervical disease and cervical cancer.

The cost of offering self-sampling is more than offset by the savings made on the cost of the treatment for cervical disease or cervical cancer that is prevented by this initiative.

## Aims

The Quality Improvement Prototype aims to enable the Cytology laboratory failsafe system to reduce the number of patients who DNA from the current level of 15% to 5% or less by 31 December 2019. It is anticipated that the number of DNA patients who are at high-risk of cervical disease (those who test HPV positive) can be reduced by offering self-sampling to this population. Analysis of the DNA rate and the rate of cervical disease or cancer in this population will determine if any changes have led to improvement.

## Methodology

IHI Model for Improvement allows the Cytology team to set a clear aim, agree measures, use PDSA cycles to plan small changes, test their impact and monitor if each small change has resulted in an improvement or otherwise, ultimately leading to implementation and improvements in the longer term. This methodology for improvement is being promoted across the Western Health and Social Care Trust.

## Measures

The current DNA rate for patients either on a first referral to Colposcopy because of an abnormality identified on Cytology, or due to have a follow-up appointment at Colposcopy or their GP is approximately 15%. On average there are 832 patients per year referred to Colposcopy or on follow-up. Referrals are recorded on a Direct Referral Database. The Cytology Audit Officer periodically checks (on a three-monthly basis) if a referred patient has attended Colposcopy or had a follow up smear with their GP. The DNA rate is calculated from this database based on the number of Colposcopy referrals or follow up appointments divided by the number of patients that DNA these appointments. The difference in the DNA rate is calculated by comparing the reduced number of DNAs as a result of the self-sample offer compared to the baseline rate before the intervention.

The intervention will include patients who have defaulted in the last five years. Directly comparing the DNA rate during the intervention period against the same period in previous years was discounted as there were several key changes and events in cervical screening over the last number of years that would have confounded the data. The most notable event was the high-profile diagnosis and death from cervical cancer of the TV celebrity Jade Goody which influenced women's decisions about cervical screening. Inclusion of a control group could not be used as it was anticipated that the number of

cases in each group, if the DNA patients were split into two separate groups, would have been too low to be statistically significant.

**Interventions**

**Normal practice** – When the Cytology Pathologist refers a patient for Colposcopy this is entered into a Direct Referral Database. The Cytology Audit Officer will then follow the patient's journey until they have their first appointment with Colposcopy. If the patient does not attend two consecutive Colposcopy appointments the Colposcopist will normally dictate a letter discharging the patient and the Audit Officer and the patient's GP will get a copy of the discharge letter. This letter will be kept on file and the Audit Officer will periodically check (approximately every 3 months) if they have attended Colposcopy or had a follow up smear with their GP.

**Planned Intervention** – The Cytology laboratory will seek permission from the GP/Colposcopist to offer the patient the opportunity to carry out a vaginal self-sample for HPV testing to help to determine the patient's risk of cervical disease (HPV positive patients have a higher risk than patients who test HPV negative), and hopefully encourage them to attend for their cervical appointment thus reducing the DNA rate for Colposcopy / follow-up appointments.

The Cytology Audit Officer will write to the patient's GPs/Colposcopists to ask for permission to offer their patient the opportunity to carry out a self-sample (Please see Figure 1).

**Western Health & Social Care Trust**
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**IN CONFIDENCE**

03/09/19

Dr Burns

Foyleside Family Practice

Bridge St. Med Centre

Bridge St.

L'DERRY, BT48 6LD

Dear Dr Burns

**PATIENTS NAME:** MS XXXX **DOB:** 17/11/1982

**ADDRESS:** XXXXXXXX LONDONDERRY COUNTY LONDONDERRY BTXX XXX

**HOSP No:** AH ***** **H+C No:** 345 *** **** **CLINIC DATE**: 11/09/17 - DNA

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This patient was discharged from the colposcopy clinic at Altnagelvin in 2018 following treatment for CIN III. She did not attend for follow up and was discharged.

We wish to send this patient a HPV self-sampling kit to assess her risk of cervical disease by testing for HPV. An invitation to self-sample, or testing positive for HPV often encourages patients to attend for follow-up appointments.

The Laboratory will be sending this patient a SELF-SAMPLING kit in the next few weeks. If you do not wish this patient to receive a self-sampling kit, please inform the Laboratory on 028 71611140 or email sarah.ross-lyttle@westerntrust.hscni.net at your earliest convenience.

Thank you.

Yours sincerely

**Sarah Ross-Lyttle**

**For Dr Mary McMenamin**

**Section Lead Molecular Science**

Figure 1. Letter sent to GPs / Colposcopists requesting permission to invite patients to self-sample

The Cytology laboratory will post study packs to potential participants, unsolicited, as previous research has shown that this is the most effective invitation model to maximize uptake.[11] Over a period of approximately one year, potential participants will be sent a self-sampling pack containing the Evalyn brush self-sampling device (Figure 2).

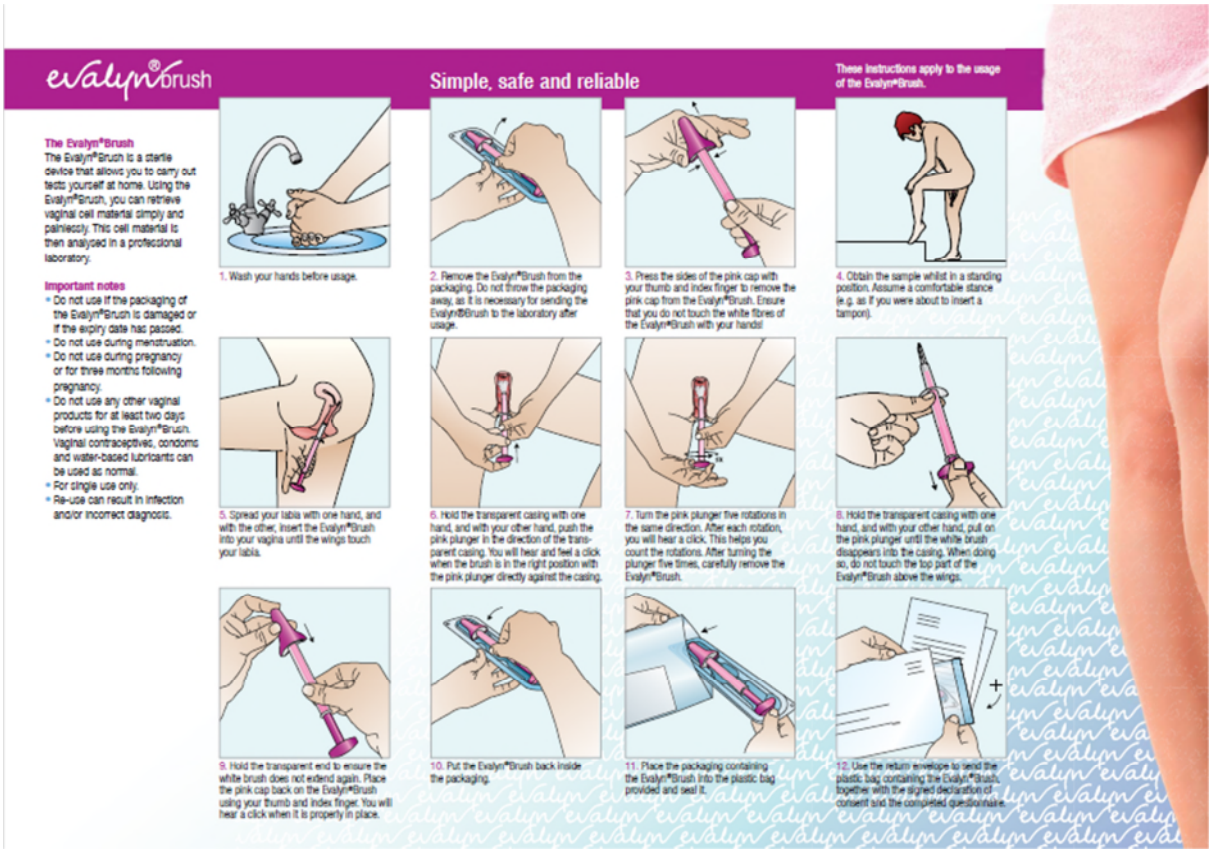


Figure 2. Evalyn Brush Instructions for Use

The study packs will contain: patient invitation letters (Figure 3), HPV self-sampling devices/instructions and return sample packaging.

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**IN CONFIDENCE**

01/05/19

MS *****

**********, DERRY, BT48 ***

Dear MS ***

**HOSP No:** AH **** **H+C No:** 376 *** ****

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**Cervical Screening:**

**Invitation to collect a SELF-SAMPLE for HPV testing**

We are writing to you because our records show that you are not up-to-date with your follow-up cervical cytology test (smear test). We understand that there are reasons why some people do not attend for cervical tests; therefore we would like to offer you the opportunity to self-collect a vaginal sample at home. Your GP has given the Laboratory permission to send you a self-sampling kit to test for human papillomavirus (HPV). Most people get HPV at some point in their lives, and in most cases your body will get rid of the virus without you ever knowing you had it. However, HPV is also linked to the development of abnormal cervical cells and in a very small number of people these cells could go on to develop into cervical cancer if left untreated. If your sample tests HPV positive you will therefore be advised to attend for a smear test.

**If you do not wish to accept this self-sampling offer** you do not have to do anything in response to this invitation. You can dispose of the enclosed self-sampling device in the normal household waste.

**If you wish to accept this self-sampling offer** please collect a vaginal self-sample and return it to the laboratory for HPV testing. Instructions for sample collection and return of samples are provided with the enclosed self-sampling device.

Your HPV result and management recommendations will be available from your GP within 2 weeks of the laboratory receiving your sample.

Yours sincerely

Sarah Ross-Lyttle

For **Dr Mary McMenamin**

**Lead Molecular Science**

*Cc.*

*Dr Deane*

*Northside Med Pract, Shantallow Hc*

*Racecourse Rd, LONDONDERRY*

Figure 3. Invitation letter to the patient to collect a self-sample for HPV testing

Participants will be asked to collect a vaginal self-sample and return it to the Cytology laboratory at Altnagelvin hospital for HPV testing. If potential participants do not wish to participate, study packs can be disposed of in the household waste (except the personal invitation letter which requires confidential disposal).

1. The patient invitation letter will explain the purpose of the initiative, how the test is conducted, by the patient and at the laboratory, how the results will be conveyed to the patient and her GP and the implications of the HPV test result.

2. The sample will be transferred to a liquid-based Cytology vial (ThinPrep) and HPV tested (cobas 4800 High-Risk HPV Test) by the project team and the results sent to the patient's GP/Colposcopist.

3. If a patient tests HPV positive it is advised that they attend for cervical Cytology although patient management is the responsibility of the GP/Colposcopist.

4. The result of the HPV self-sample will be recorded on the LabCentre patient database as for all other cervical test results.

**Results**

GPs and Colposcopists consented to 160 self-sample invitations sent to DNA patients from May 2019 to March 2020. There were 21 kits returned to the laboratory by DNA patients for HPV testing (13% uptake of the self-sampling offer). Table 1 below details the default history for each patient and demonstrates the effect of the HPV result on patient action. The final outcome for each patient is also recorded.

The age range for patients was 26 to 64 years old. Most patients who defaulted from Colposcopy investigation and possible treatment had low-grade findings on Cytology (borderline) except for one patient who had a finding of moderate dyskaryosis which is treated as a high-grade abnormality.

Five patients DNA their follow-up appointment which was indicated due to a previous inconclusive result. There were three patients that DNA Colposcopy follow-up after treatment for CIN3 and three patients DNA GP follow-up following treatment for CIN1.

There were ten self-samples patients that tested HPV negative and were therefore advised to attend for their next routine recall appointment. Two of these patients attended for a smear immediately without waiting for their next recall appointment.

There were 11 HPV positive self-samples and all patients attended immediately for their smear. Of these 11 patients, six had a negative Cytology or subsequent HPV test and were returned to routine recall if HPV negative or 12-month recall if HPV positive. One patient's smear was unsatisfactory; this patient was referred for gynaecological investigation; however, there is no outcome available to date. There were two HPV positive patients that had moderate or severe dyskaryosis findings on Cytology and both were found to have CIN3 which was treated at Colposcopy. Two HPV positive patients that had BL or negative Cytology were treated for CIN1 at Colposcopy.

From an average of 832 patients per year referred to Colposcopy or on follow-up, there was an average of 124 patients that DNA therefore the DNA rate before the intervention was approximately 15% (124/832). Following the intervention, there was a 3% reduction in the DNA rate as demonstrated by the 21 patients who took up the offer to self-sample reducing the rate to 12% (103/832). This percentage reduction is less than the anticipated value of less than 5%.

Table 1. Summary of default history and outcomes for patients who have taken up an invite to self-sample when offered by GPs or Colposcopists

| Patient | Age | Default History | HPV Self-Sample Result | Patient Action | Patient Outcome |
|---|---|---|---|---|---|
| 1 | 26 | BL 2016; DNA GP follow-up | Negative 2019 | NA | Due routine recall smear 2022 |
| 2 | 30 | BL 2015; DNA Colposcopy | Negative 2019 | Attended for smear 2019; Negative | Due routine recall smear 2022 |
| 3 | 27 | Treated CIN1 at Colposcopy 2017; DNA GP follow-up | Negative 2019 | Attended for smear 2019; Negative | Due routine recall smear 2022 |
| 4 | 31 | Treated CIN1 at Colposcopy 2017; BL 2018; DNA GP follow-up | Positive 2019 | Attended for smear+HPV test 2019; BL, HPV Negative | Due routine recall smear 2022 |
| 5 | 62 | BL 2009, Inadequate 2014; DNA GP follow-up | Negative 2019 | NA | Due routine recall smear 2022 |
| 6 | 55 | BL 2014; DNA GP follow-up | Positive 2019 | Attended for smear 2019; Severe dyskaryosis | CIN 3 treated at Colposcopy |
| 7 | 28 | Inadequate 2016; DNA GP follow-up | Positive 2019 | Attended for smear 2019; Moderate dyskaryosis | CIN 3 treated at Colposcopy |
| 8 | 31 | Treated CIN1 at Colposcopy 2014; DNA GP follow-up | Positive 2019 | Attended for smear+ HPV test 2019; Negative, HPV Positive | Due early 12-month recall smear 2020 |
| 9 | 32 | BL, HPV Positive 2014; DNA Colposcopy | Positive 2020 | Attended for smear 2020; Negative | Due early 12-month recall smear 2021 |
| 10 | 32 | CIN3 treated at Colposcopy 2015; DNA Colposcopy follow-up | Negative 2019 | NA | Due routine recall smear 2022 |
| 11 | 35 | CIN3 treated at Colposcopy 2016; DNA Colposcopy follow-up | Negative 2019 | NA | Due routine recall smear 2022 |
| 12 | 42 | CIN3 treated at Colposcopy 2014; DNA Colposcopy follow-up | Negative 2019 | NA | Due routine recall smear 2022 |
| 13 | 59 | Moderate dyskaryosis 2018; DNA Colposcopy | Negative 2019 | NA | Due routine recall |

| | | | | | |
|---|---|---|---|---|---|
| | | referral | | | smear 2022 |
| 14 | 50 | Inadequate Colposcopy 2015; DNA Colposcopy follow-up | Negative 2019 | NA | Due routine recall smear 2022 |
| 15 | 64 | Inadequate 2017; DNA GP follow-up | Positive 2019 | Smear Negative 2019 | Due early 12-month recall smear 2020 |
| 16 | 28 | BL 2016; DNA GP follow-up | Positive 2019 | Smear BL 2019 | CIN1 treated at Colposcopy |
| 17 | 28 | BL, HPV Positive 2018; DNA Colposcopy referral | Positive 2019 | Smear Negative 2019 | Due early 12-month recall smear 2020 |
| 18 | 63 | Inadequate 2014; DNA GP follow-up | Positive 2019 | Smear Negative 2019 | CIN1 treated at Colposcopy |
| 19 | 57 | BL 2015; DNA GP follow-up | Positive 2019 | Smear Negative 2019 | Due early 12-month recall smear 2020 |
| 20 | 34 | BL, HPV Positive 2017; DNA Colposcopy referral | Negative 2019 | NA | Due routine recall smear 2022 |
| 21 | 57 | Unsatisfactory smear history; DNA Colposcopy referral | Positive 2020 | Unsatisfactory smear 2020 | Referral to Gynae; no outcome available to date |
| | | | | | |

*BL; borderline changes in Cytology. Moderate/Severe Dyskaryosis; high-grade abnormality found on Cytology normally corresponds with CIN2/3 respectively.*

## Discussion

The study found that following the intervention there was a 3% reduction in the DNA rate reducing the rate from 15% to 12%. This percentage decrease is less than the anticipated value of less than 5%. However, the DNA patients in this intervention were from a retrospective cohort (stretching back over five years) that included patients who hadn't responded to several reminders to attend appointments; therefore it is assumed that this cohort were less likely to accept the offer to self-sample than if the patients had defaulted more recently.

Perhaps if the intervention came earlier to patients who DNA they might be more responsive to self-sampling invitations. Our own self-sampling study that concentrated on patients who had recently defaulted found that there was a 16% uptake in self-sampling offer; that is 3% higher than the current initiative.

This study also showed that those who test HPV positive, and therefore have an increased risk of cervical disease, are more likely to attend their GP or Colposcopy for initial or follow-up investigation and treatment if necessary. All of the 11 patients who tested HPV positive on their self-samples attended immediately for their smear. Of these 11 patients, six had a negative Cytology or subsequent HPV test and were returned to routine recall if HPV negative or 12-month recall if HPV positive. One patient's smear was unsatisfactory; this patient was referred for gynaecological investigation; however, there is no outcome available to date. There were two HPV positive patients who had moderate or severe dyskaryosis findings on Cytology; both attended Colposcopy and were found to have CIN3 which was subsequently treated. Two HPV positive patients who had borderline or negative Cytology attended Colposcopy and were treated for CIN1.

## Conclusion

This Quality Improvement Prototype aimed to enable the Cytology laboratory failsafe system to reduce the number of patients who DNA their GP or Colposcopy for initial or follow-up investigation.
Previous studies have shown that patients who DNA for cervical appointments are more willing to self-collect a vaginal sample for HPV testing to determine their risk of cervical disease [2, 3] and if they test HPV positive they are more likely to attend for cervical investigation.[4] Furthermore, vaginal self-sampling has undergone extensive research and it has demonstrated sensitivity to detect cervical disease that is equivalent to that of clinician-collected samples.[8-10, 14]

The laboratory therefore embarked on an initiative to decrease the DNA rate in people referred to Colposcopy or on follow up for cervical abnormalities. Overall the project has demonstrated a degree of success that could be improved with further investment. Of particular note is the 2 self-sample, HPV positive patients found to have CIN3 at Colposcopy. It is possible that these patients were at significantly increased risk of developing cancer if not for this intervention.

The findings of this initiative are consistent with the findings of the self-sampling pilot study conducted by our own laboratory as previously outlined. The laboratory has therefore continued to advise GPs and Colposcopists to offer self-sampling to patients who default referral or follow-up appointments in an effort to continually reduce DNA rates and subsequently cervical disease and cancer. A more widespread uptake of this initiative by patients, as well as several years of patient history follow-up will be required before a significant reduction in disease or cancer can be reliably established.

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